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# BREAST CANCER SCREENING FOR MEDICARE BENEFICIARIES:

# EFFECTIVENESS, COSTS TO MEDICARE AND MEDICAL RESOURCES REQUIRED

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*for Medicare Beneficiaries:*
*Effectiveness, Costs to Medicare and Medical Resources Required*

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# Breast Cancer Screening for Medicare Beneficiaries: Effectiveness, Costs to Medicare and Medical Resources Required

## PART I: INTRODUCTION AND SUMMARY

Should Medicare coverage be available for breast screening? The question is a complicated one. This staff paper, requested by the Senate Labor and Human Resources Committee, examines that question and presents its findings.

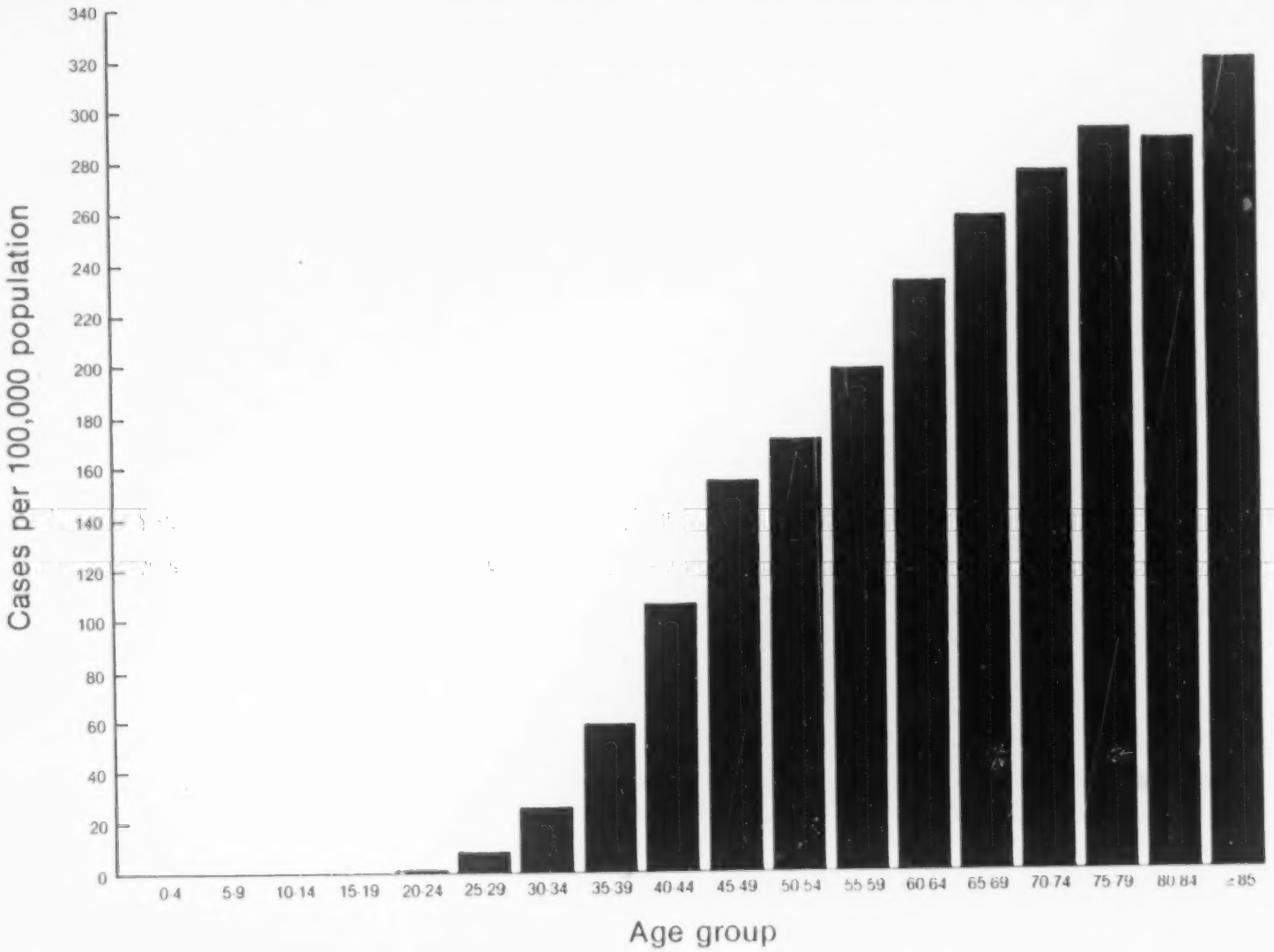
Breast cancer is the leading cause of cancer deaths among women, and it primarily afflicts older women. In fact, the chances of acquiring breast cancer increase with age (see figure 1); the 65 and older age group is about one and one-half times as likely as the 40-64 age group to have breast cancer. In 1987 alone, about 48,000 (44 percent) of the new primary cases of breast cancer will occur in women over 65 (Health Technology, 1987),[1] and about 24,000 women 65 and over will die from the disease.

Although epidemiological evidence has suggested a number of risk factors for breast cancer, the cause of this virulent disease is not known. Early detection--typically involving breast physical examination and mammography--has thus been heralded by the American Cancer Society and other health organizations as the best means of preventing the debilitation and death that result from advanced breast cancer.

But third-party payment, including Medicare reimbursement, is not generally available for screening examinations.[2] Insurers, including the Federal Government, have been concerned that the cost of reimbursement for such examinations would be high, relative to the exams' effectiveness in detecting breast cancer. In addition, Medicare benefits are limited primarily to covering illness <u>after</u> diagnosis. Medicare pays for only two primary prevention activities--vaccinations for pneumococcal pneumonia and hepatitis

Figure 1

## NEW PRIMARY BREAST CANCERS—1987




SOURCE: OTA, Calculated by Dr. David Eddy based on data from NCI, SEER.

B.[3] Concern has also been expressed about the safety of mammography procedures and the availability of the necessary resources should a widescale screening program begin.

The Senate Labor and Human Resources Committee, concerned primarily about older women--the group most at risk and the group with a Federal medical care program already in place--asked OTA to examine the following questions:

o Is breast cancer screening a safe and effective means of reducing premature mortality in the female Medicare population?

o What would be the net costs to Medicare of paying for breast cancer screening for Medicare beneficiaries? and

o Are the equipment and medical staffing resources for providing such a benefit available?

As part of our analysis, we also evaluated whether there is a need for a screening reimbursement for Medicare beneficiaries or whether women 65 and older are already participating in screening programs to the extent possible.

Our analysis of the effectiveness of breast cancer screening was limited to women 65 and older and to the costs and cost-savings that Medicare could expect should breast cancer screening be reimbursed. We did not focus on costs or savings to society as a whole or to individual women, although we touched upon these areas.

This introduction summarizes the way we proceeded with our analysis and the results of that analysis. Other sections will provide more details and give the results of a range of assumptions about breast cancer screening for Medicare beneficiaries.

## The Need for Screening

We found that despite advances in detection and treatment in recent years, breast cancer remains a common and particularly virulent disease of

women in the United States in medical, emotional, social, and economic terms.

In its early stages (Stages 0, I, and part of Stage II), breast cancer is a relatively curable disease. Unlike lung and some other cancers, breast cancer is relatively indolent, that is, it takes longer to develop, and a diagnosis is less likely to mean an almost sure death sentence. However, if left undiagnosed until its later stages, breast cancer is more likely to spread to other sites in the body and cause premature death. The emotional impact of being diagnosed with an advanced-stage breast cancer and the social and financial impact on families, friends, and co-workers can be devastating.

Advanced-stage breast cancer will likely involve the use of chemotherapy or radiotherapy or both, in addition to surgical removal of all or part of the breast and other tissues. These treatment methods are both expensive and can cause considerable side effects, adding to the morbidity and suffering involved with breast cancer. There is also a significant emotional component to the loss of a breast, no matter what the woman's age. If breast cancer is diagnosed at an early stage, there is considerable evidence that life can be prolonged, and severe morbidity and its associated medical, emotional, and economic costs can be avoided in many patients.

One might expect that women would be concerned enough to be screened regularly for breast cancer. But our review of available information indicated that most women are not screened regularly for breast cancer. There are several reasons why breast cancer screening is underutilized by women in all age groups:

- Relatively few women are examined for breast cancer by their physicians or referred for screening mammograms;
- Fears about excess radiation persist;
- Fear of a cancer diagnosis is a deterrent; and
- The expense may be prohibitive.

As noted earlier, the cost of mammography alone is usually not covered by insurance, and it ranges from about $40 to $100, $200, or even more. A breast physical examination, which is deemed an essential adjunct to mammography, is usually an additional cost. These charges may make breast cancer screening financially out of reach, especially for the 15 percent of women 65 and older who exist at or near the poverty level of about $6,000 a year (U. S. Department of Commerce, 1985; The Villers Foundation, 1987).

Taking all these factors into consideration, it is perhaps not surprising, then, that all available evidence indicates that the older the woman, the less likely she is to perform breast self-examination, have an annual clinical breast examination, or have an annual mammogram. For example, in 1985, it seems only 4 percent of Medicare enrollees received mammographic examinations paid by Medicare; most of these are believed to be diagnostic, rather than screening, mammograms (USDHHS, HCFA, 1987). (Diagnostic exams are conducted on patients who show symptoms, such as a lump in the breast; screening examinations are typically done on asymptomatic patients[4].) As a result of the lack of screening, older women are more likely to be diagnosed with advanced-stage breast cancer (Allen et al., 1986).

## Effectiveness and Costs of Breast Cancer Screening

### Sources and Assumptions

OTA used a variety of sources to estimate the effectiveness and costs of breast cancer screening for Medicare beneficiaries. A summary of the assumptions derived from these sources is shown in Table 1. Briefly, the assumptions are the following:

- We assumed that screening reduces mortality 50 percent at five years, and this effect gradually decreases to 30 percent at 20

Breast Cancer Screening
for Medicare Beneficiaries:
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## TABLE 1
## SUMMARY OF ASSUMPTIONS FOR BASE CASE ANALYSIS

- Screening includes annual breast physical examination (BPE) and mammography
- The combined false-positive rate of the two examinations is 2%.
- 30% of women aged 65-74[1] offered screening will accept.
- The group of women who accept screening have an average risk of developing breast cancer.
- Screening reduces mortality by 50% at five years, gradually decreasing to 30% at 20 years[2]
- Shifts in stages were chosen to achieve the assumed reduction in mortality at each followup period.[3]
- Costs to Medicare:

| | |
|---|---|
| Screening mammogram and BPE | $ 50 |
| Workup for false positive | $ 900 |
| Difference in Costs of Initial treatment[4] between Stages 0 and IV | $ 1,200 |
| Continuing care (per month)[5] | $ 183 |
| Terminal care - breast cancer | $ 10,776 |
| Terminal care - other causes | $ 7,618 |

- Women accepting screening would already have paid their $75 deductible as a result of receiving other care.

Source: OTA.

*Notes to Table 1:*

[1] This age group is believed to be the most likely to accept screening, and the group with the most to gain from screening because of their longer life expectancy.

[2] Because none of the research studies matches the target population precisely, there is considerable uncertainty about the actual effectiveness of screening in reducing mortality. The baseline assumption is one estimate made to indicate the approximate magnitude of the effect. It is based loosely on results of the HIP study (Shapiro et al, 1985) but includes consideration of 4 other controlled studies of screening.

[3] Shifts in Stage Achieved by Screening[a]

| | Stage Proportions: Without Screening | With Screening |
|---|---|---|
| Stage 0 | 0.051 | 0.050 |
| Stage I | 0.248 | 0.400 |
| Stage II | 0.534 | 0.550 |
| Stage III | 0.081 | 0.000 |
| Stage IV | 0.086 | 0.000 |

[a] There are no data from controlled trials on how screening changes the proportion of cancers detected in each stage for women age 65 and over. For purposes of estimating changes in morbidity, we considered the results of the Breast Cancer Detection Demonstration Project (BCDDP) (Seidman et al., 1987) which is the only project which reported results by stage. However, BCDDP was not a controlled study and the reported results apply to women over 50 (not 65) so the estimate of late stage cancers avoided that is derived from BCDDP may be somewhat overstated.

[4] Defined as care delivered in the first three months followed diagnosis.

[5] Difference between cost of breast cancer and cost of other causes of death.

years. Shifts in stages were chosen to achieve the assumed reduction in mortality at each follow-up period.

- Costs of screening to Medicare were estimated from Medicare data (USDHHS, HCFA, 1987), current practices, and assumptions about future practices. A key assumption for our base case analysis was that screening--including a breast physical examination and a mammogram[5]--could be obtained for $50, or that Medicare would restrict payment to that amount. Although the cost of a mammogram alone (in centers that do not distinguish between charges for screening and for diagnostic mammograms) can be more than $200, a small number of breast screening programs have shown that a combination of medical history-taking, breast physical examinations, instruction in breast self-examination, and even follow-up can be provided for $25 to $45 (Bird & McClelland, 1986; Sickles, 1986; Strax, 1984, 1987). This cost assumption may mean that someone who is not a physician but is technically trained would perform the breast physical examination.

- We also assumed that women accepting screening would have already met their $75 deduction for an office visit as a result of another encounter during the year they were screened.

- One of our assumptions that increased the net costs of screening is the number of false positive examinations that would result in a recommendation for a biopsy. We assumed that 2 percent of the screening examinations would result in a recommendation for a biopsy, and the cost to Medicare of these additional biopsies due

to false-positive screening examinations would be $900 per workup.[6]

A key expectation of a cost-effectiveness analysis of a prevention program such as breast cancer screening is that prevention results in savings due to lower costs of treatment. Thus, it was central to our analysis to estimate a reduction in costs to Medicare that might result by detecting more cancers at earlier, and thus less costly, stages. Unfortunately, there are no Medicare data on cost-per-stage of the illness.

- Available data indicated the following: 1) there was a difference of about $1,200 between initial treatment for Stage 0 breast cancer (carcinoma in situ) and Stage IV breast cancer; 2) the breast cancer-specific cost to Medicare for continuing care was $183 per month; and 3) the cost to Medicare for terminal care[7] for breast cancer was $10,776, and for all other causes of death $7,618.

  These are the best and most complete current estimates of the costs to Medicare of breast cancer diagnosis and treatment, based on an extensive analysis of Medicare data by the National Cancer Institute (Baker, Kessler and Smucker, 1987; in preparation). However, we should emphasize that NCI's analysis was conducted with data collected between 1974 and 1981 and may not reflect current treatment. In addition, there are many costs of breast cancer diagnosis and treatment that are borne either by the individual patient or by "Medigap" insurance, which reimburses patients (or providers) for charges not paid by Medicare.[8] These costs have not been collected or analyzed systematically.[9]

Other important factors in estimating the effectiveness and costs to Medicare of breast cancer screening are the proportion of women who are screened and the frequency with which they are or can be screened. As noted earlier, the proportion of women 65 and older who are screened regularly for

breast cancer appears to be extremely low. Among women older than 45, different studies have found the use of regular breast cancer screening to be 2 percent,[10] 5 percent[11], or 15 percent.[12] These and other studies indicate that the use of mammography decreases with age; however, none of them reported the use of mammography by women 65 and older as a separate group. In contrast to these low utilization rates, 80 percent of women in a recent study in Sweden participated in regular screening (every 2-3 years), and fifty percent of women offered screening in a U.S. study conducted by an organized health care plan in the 1960s participated, demonstrating, perhaps, that an organized effort to have women participate in screening can be effective.

- For our base case analysis, we assumed that women ages 65 to 74 would be the most likely to accept screening, and that 30 percent of asymptomatic women in that age group would be screened annually if fees were reimbursed.
- Finally, we assumed that the screening program would begin in 1987, and that treatment for breast cancer is effective.

Calculation Method.

A computerized mathematical model developed by Dr. David Eddy of Duke University, in conjunction with the National Cancer Institute and their advisors, was used by Dr. Eddy, under contract to OTA, to estimate the effectiveness and costs of screening. The calculation methods are complicated and are described more fully in Part III of this staff paper and in Eddy (1986). Briefly, the computer model projects what would happen if a screening program were introduced in a population, keeping track for each year of such outcomes as how many women are eligible for screening, how many are diagnosed as having breast cancer (by stage), how many carry the diagnosis of breast

cancer, and how many die of breast cancer or other causes. It also calculates the financial costs associated with the important events (e.g., screening, workups, treatment).

Results

Life-years Saved and Suffering Avoided. As shown in the summary table (Table 2), the base case analysis estimated that a screening program begun in 1987, in which 30 percent of female Medicare beneficiaries ages 65 to 74 accepted annual screening, would result in the avoidance of about 2,500 advanced-stage breast cancers every year from 1990 to 2020, with a total of 85,041 advanced-stage breast cancers prevented and 268,000 life-years saved by 2020.

Statements about the effectiveness of screening can be confusing, because the effects depend on several factors, such as the population denominator (e.g., those screened versus the entire at-risk population), the assumptions made about the proportion of women who accept screening, and the frequency with which they are screened.

For example, there would be a 3.5 percent reduction in breast cancer deaths (that is, 828 fewer breast cancer deaths) in the year 2000, if 30 percent of women ages 65 to 74 were screened annually--the assumption made in our base case analysis. If all women 65 and older were screened annually, there would be 5,200 fewer breast cancer deaths in 2000, a reduction of 22 percent in this age group. The Federal Government has set itself a goal of reducing deaths from all cancers in all age groups by 50 percent by the year 2000 (USDHHS, NCI, 1986). Thus, it seems that regular breast cancer screening would help to meet this goal.

In terms of an individual average-risk 65-year-old woman (that is, one who has only a 5 percent chance of developing breast cancer in the rest of her life), who is screened annually from ages 65 to 74, the increase in life

## TABLE 2

## BREAST CANCER SCREENING FOR MEDICARE BENEFICIARIES AGED 65 AND OVER IS EFFECTIVE

## SELECTED SUMMARY RESULTS FOR EFFECTIVENESS

| | |
|---|---|
| **DEATH AND SUFFERING AVOIDED WITH ANNUAL SCREENING OF 30% OF WOMEN 65-74[1]** | |
| Breast Cancer Deaths Prevented in 2000 | 828 |
| Percent Reduction in Breast Cancer Deaths in 2000 | 3.5% |
| Cumulative Number of Late Stage Cancers Avoided by the Year 2020 | 85,000 |
| Cumulative Number of Person Years of Life Saved 1987-2020 | 268,000 |
| **DEATH AND SUFFERING AVOIDED IN 2000 WITH ANNUAL SCREENING OF ALL WOMEN 65 AND OLDER** | |
| Number of Breast Cancer Deaths Avoided in 2000 | 5,200 |
| Percent Reduction in Breast Cancer Deaths | 22% |
| **RISK TO AN INDIVIDUAL WOMAN OF ACQUIRING A NEW CASE OF BREAST CANCER DUE TO MAMMOGRAPHIC X-RAYS** | Less than 1 in 500,000 |

[1] See Table 1 for summary of other assumptions used in the base case analysis.

expectancy is about 13.4 days. For a woman destined to get breast cancer after age 65, such a screening regimen would increase her expected lifetime by 258 days and would reduce the probability she would die of breast cancer by about 19 percent.

Costs to Medicare. As far as costs to Medicare are concerned, all assumptions used in our analysis showed that breast cancer screening cannot be expected to save enough money in decreased treatment costs to offset the costs of screening and workups. There are savings due to a reduction in initial and terminal treatment costs for breast cancer (see Table 3), but the cost of screening far exceeds these savings. In addition, there are the costs of workups due to additional false positive results as well as costs of continuing management and treatment for those women kept alive longer with a diagnosis of breast cancer. For example, screening 30 percent of women ages 65 to 74 will involve testing about three million women each year and working up approximately 55,000 women each year for false-positive test results.

Our base case analysis found that a breast cancer screening program would cost Medicare about $185 million in 1990 (if costs were undiscounted)[13] or $160 million (if costs were discounted at 5 percent). The cost to Medicare per life-year saved by 2020 is approximately $28,000, undiscounted, or $13,200 if costs are discounted.

To help put these potential estimated costs in context, $185 million represents less than one-twentieth of one percent of the projected $320.8 billion of Medicare expenditures in the year 2000 (USDHHS, HCFA, Division of National Cost Estimates, 1987). On the other hand, if all women 65 and over accepted screening, the net cost to Medicare in 1990 would be $1.5 billion (still less than one-half of one percent of projected Medicare expenditures in 2000).

Biennial Screening. The effects of biennial mammograms and breast

## Breast Cancer Screening for Medicare Beneficiaries:

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### TABLE 3

### SELECTED SUMMARY RESULTS FOR NET COSTS AND COST EFFECTIVENESS TO MEDICARE[1]

**COSTS TO MEDICARE WITH ANNUAL SCREENING OF 30% OF WOMEN 65-74**

**ESTIMATED FINANCIAL COSTS TO MEDICARE IN 1990**

| | Without Discounting | With 5% Discounting |
|---|---|---|
| Screens | $138,600,000 | $119,800,000 |
| Workups | 49,900,000 | 43,100,000 |
| Initial Treatment | -1,000,000 | -900,000 |
| Continuing Treatment | 3,500,000 | 3,000,000 |
| Terminal Treatment - Cancer | -6,200,000 | -5,300,000 |
| Terminal Treatment - Other | 300,000 | 200,000 |
| Annual Net Cost to Medicare in 1990 | $185,100,000 | $159,900,000 |
| **COST-EFFECTIVENESS TO MEDICARE** | | |
| Cost per life-year saved[2] by 2020 | $ 28,000 | $ 13,200 |

1 See Table 1 for Assumptions of the Base Case Analysis.

2 Health effects not discounted. Disagreement exists among analysts about whether health effects should be discounted in cost-effectiveness analysis. Under an assumption in which both cost and health effects would be discounted, the cost to Medicare per life-year saved by 2020 would be approximately $34,600.

physical examinations have been estimated under the assumption that biennial examinations will deliver 75 percent of the effectiveness of annual examinations. In the year 2000, there would be about 600 fewer breast cancer deaths and 1,800 fewer late stage cancers under biennial screening, instead of 830 fewer deaths and 2,300 fewer late stage cancers under annual screening. Of course, biennial screening would reduce the cost of screening, the number of false positive results, and the cost of workups each year by a factor of two. We estimate that the discounted net cost in 1990 for biennial screening, if 30 percent of women ages 65 through 74 accepted screening, would be $79 million, half that of annual screening of the same group.

## Medical Resources for Screening

It is, of course, not possible to predict the precise number of screens that would be done if reimbursement were available, but OTA found no evidence of a current shortage of breast-cancer screening services in the United States; on the contrary, it appears that resources for breast cancer screening are underutilized, in part because neither women nor their physicians follow current recommendations regarding screening. Our summary of the availability of and requirements for health care personnel and mammographic equipment under an assumption of annual screening, with 30 percent of women ages 65 to 74 accepting screening, are shown in Table 4. This table also shows the requirements should 100 percent of women 65 and older accept breast cancer screening.

In our analysis of the resources required for screening, one of our key assumptions was that, as a number of breast screening centers have demonstrated, one dedicated screen-film mammographic machine can perform an average of 30 examinations per 8-hour day, or about 7,500 examinations a year. We also assumed that three radiological technologists can manage a free-

## Breast Cancer Screening for Medicare Beneficiaries: Effectiveness, Costs to Medicare and Medical Resources Required

### TABLE 4.--SUMMARY OF RESULTS FOR MEDICAL RESOURCES REQUIRED

**IN GENERAL, RESOURCES ARE ADEQUATE**

| RESOURCES REQUIRED IN 1990 | Available Now | Base Case Estimate[1] Requirements[2] | Maxiumum Requirements[2] |
|---|---|---|---|
| *Number of screening examinations* | | *2.8 million* | *17.4 million* |
| Dedicated[3] mammography units[4] | 4,900[5] | 460 | 2,323 |
| Diagnostic radiologists[6] | 13,000[7] | 60 | 290 |
| Radiological technologists[8] | 160,000[9] | 1,400 | 6,970 |
| Health professionals qualified to do breast physical examinations[10] | 409,000[11] | 1,700 | 10,900 |

1 See assumptions in Table 1. Basically, the base case assumes annual screening for 30% of asymptomatic women 65-74 years old.

2 To adjust for the geographic distribution of the population aged 65 and over (approximately 26% rural [U. S. Department of Commerce, Bureau of the Census, 1985]), we multiplied the number of machines and health professionals required to perform breast physical examinations by a factor of 1.25.

3 Dedicated means used only for mammography and not for other radiologic diagnostic purposes.

4 Assumption is that one mammography machine performs approximately 30 examinations daily or 7,500 examinations a (250 workday) year.

5 Source: American College of Radiology, the U. S. Food and Drug Administration, and other sources cited in OTA's forthcoming staff paper.

6 Assumption is that screening mammograms can be interpreted by radiologists at the rate of approximately 30 per hour: that is, the average daily output of one mammography machine, 30 examinations, can be interpreted in 1 hour of a radiologist's time, or in 12.5 percent of a radiologist's 8 hour day. Put more simply, the number of machines divided by 8 gives the number of radiologists required to meet the assumed demand.

7 This figure includes all diagnostic radiologists. Source: American Medical Association and other sources cited in OTA's forthcoming staff paper.

8 Each mammography machine is operated by a staff of three radiological technologists (or similar staff).

9 As with diagnostic radiologists, this includes all radiological technologists, not just those who may subspecialize informally in mammography. The figure may be an underestimate because it includes only those registered with the American Registry of Radiological Technologists.

10 Calculation for the base case estimate: 2,773,000 breast physical examinations divided by 8 per day = 347,000 person days, divided by 250 work days per year = 1,386 health professionals. This number was then multiplied by a factor of 1.25 to adjust for the geographic dispersion of the population, and rounded. For the maximum requirement, substitute 17,427,000 exams, 2,178,375 person days, and 8,714 health professionals.

11 Includes 188,000 physicians in either Family Practice, General Practice, Internal Medicine or Obstetrics/Gynecology (AMA, 1986), 15,000 nurse practitioners, 16,000 physician assistants, 2,000 certified nurse-midwives (all from OTA, Nurse Practitioners, 1986), and 188,000 registered nurses. As with radiologists and radiological technologists, the figures for health professionals qualified to perform breast physical examinations includes all available personnel. If the examination were to be performed by non-physicians, the current nurse shortage should be considered.

Source: OTA.

standing breast screening program with one dedicated mammographic machine--a liberal estimate--and that a single radiologist can evaluate 30 screen-film mammograms in an hour.

At least 4,900 dedicated mammographic machines are operating in the United States now, and more than 1,500 machines are being installed annually--a rapid pace. There is an apparent surplus of physicians in the United States, and the field of diagnostic radiology is experiencing above-average growth. Radiological technologists and other support staff can be trained as needed.

There is one exception to our estimate that an adequate level of resources is available for breast cancer screening: the availability of the health professionals that would be needed to perform breast physical examinations and instruct women in breast self-examination. Several breast screening programs have shown that nonphysicians can be trained to do at least the initial phase of the examination, although physicians would be required to assess suspicious lumps. We expect that nurses, nurse-practitioners or similar personnel would perform breast physical examinations. There is, however, an apparent shortage of nurses. Therefore, the only group of health professionals who might be in short supply are nurses.

A further caveat is that we were not able to compare the availability of resources to requirements in specific geographic areas of the country. Anecdotally, we found that some areas of the country have a greater supply of screening resources than others. In the results shown in Table 4, we made a rough adjustment for the greater resource needs required by the geographic distribution of the population.

Another consideration is that the need to monitor the quality of screening services should be anticipated, especially if Medicare expects to restrict the amount to be reimbursed to providers of screening services.

Although the Food and Drug Administration (FDA) has responsibility for monitoring x-ray emmissions in the radiographic equipment sold and installed in the United States, other aspects of breast-cancer screening procedures can affect the quality of the results. Furthermore, the rapid rise in new free-standing breast screening facilities is likely to raise concerns about the quality of the services provided. A mammography accreditation program by the American College of Radiology will establish quality standards, because most screening programs will be designed for ACR accreditation to ensure recommended listing by the American Cancer Society. This program, however, is in its beginning stages, and its actual contribution to quality screening has not been evaluated. But perhaps Medicare could decide to pay only for screening services provided in ACR-accredited facilities.

## Risks of Screening

Assuming the use of dedicated mammography equipment and quality control, the carcinogenic effect of modern mammography for women over 65 is relatively negligible. The dose currently used for mammography is (or should be) very low. If there is any risk, it is expected to cause fewer than five new breast cancer cases in one million 65-year-old women over the rest of their lives if they are screened ten times between ages 65 and 74.

There are, however, some risks associated with a false-positive breast physical exam or mammogram, which may be of concern to individual women. OTA estimates that up to 2 percent of women screened will have false positive examinations requiring additional diagnostic tests and often surgical biopsies. Although a combination of breast physical exam and mammogram is the best available noninvasive means of screening, positive results of either test must still be confirmed with a biopsy, usually a surgical one. This procedure is uncomfortable and carries with it the risk of infection and, if done under

a general anesthetic, the risk of complications associated with any surgical procedure.

## Limitations and Sensitivity of our Analysis

A number of limitations to our analysis should be considered, and other assumptions are, of course, possible.

For example, we may be underestimating the number of Medicare beneficiaries who are receiving regular screening. Medicare beneficiaries participating in HMOs and other per-capita fixed-payment plans may already be receiving breast cancer screening; Medicare would have no independent record of such screenings. However, the number of such women is small.

We may also be underestimating the potential effectiveness of treatment for women 65 and older. The impact of screening on breast cancer mortality depends on effective treatment. Breast cancer treatment has changed since the studies on which our screening-effectiveness assumptions were begun and may be more effective in the future. However, several studies indicate that older women do not receive the same level of breast cancer treatment that younger women do, even though retrospective analyses found some older women were as resilient as younger women in withstanding aggressive treatment (Chu et al., 1987; Wetle, 1987). If treatment improves in general or among older women, the impact of screening would be enhanced.

OTA's analysis was not able to consider a number of options that might be examined by the Federal Government to reduce the cost of breast cancer screening to Medicare, although this may mean shifting the cost to other payers. The costs of breast cancer screening might be less under a per-capita fixed-payment plan; some HMOs already include breast cancer screening, including mammography, as part of their benefits. Another option might be to make breast screening a public program. Such an option would probably allow

coverage for breast cancer screening only to those who cannot afford to pay for it (that is, through a means test). Medicare could also explore such an option, although there is no precedent for it in Medicare.

We could assume that 100 percent of women 65 and older would accept screening or that screening would be offered every three years, or that the various costs should be different would be different; several analyses using different assumptions as well as a method for estimating the effects of different assumptions can be found in Part III of this staff paper. It is worth noting that no matter which assumption we used, our analysis indicates that breast cancer screening for women 65 and older would be effective in terms of breast cancer deaths and morbidity avoided.

## Conclusion

As the population grows older, we can expect the number of women over 65 with breast cancer to increase. Clearly, increased use of breast cancer screening would reduce the severe morbidity, premature mortality, and, to some extent, treatment costs associated with advanced breast cancer. The lives of many women would be prolonged, and there would be considerably less suffering if most women 65 and older were diagnosed early in the disease process. Unfortunately, the number of screenings required to detect a single breast cancer is also high, and the economic cost to Medicare per breast-cancer screen, even using conservative assumptions, is high. These factors offset any savings that would be realized in treatment, resulting in a net cost to Medicare if screening were introduced. However, it seems somewhat unfair to require a relatively low-cost program like breast cancer screening to demonstrate that it is cost-effective. There are a considerable number of expensive procedures and diagnoses that Medicare covers that are sometimes performed in the absence of demonstrated need and effectiveness (e.g., USDHHS,

OIG, August 1987). The fact that breast cancer screening does not save money should not, by itself, lead to rejection of the program. Extremely few health activities, whether they are for diagnosis, treatment, or rehabilitation, save money. Indeed, the purpose of health care is to spend money to improve the health of people.

In addition, mere reimbursement for breast cancer screening may not be enough to induce women to be screened regularly. As mentioned earlier, there are a number of other reasons that women and physicians give--and there are probably reasons they are not consciously aware of--for noncompliance with screening recommendations. Whether screening is reimbursed or not, an effort to convince both women and physicians of its effectiveness seems in order.

## PART II: MEDICAL ISSUES

Breast cancer can impose severe medical emotional, social and financial burdens on women and society. This section describes the disease of breast cancer in older women, its diagnosis and treatment, and its medical, emotional, and social sequelae.

Breast cancer starts in the breast, but it may spread throughout the body. If the cancer is detected before it has spread, or metastasized, from the breast to other parts of the body, the cancer may be halted by removing the cancerous tissue. If the cancer has begun to metastasize, the chances of destroying it are greatly reduced. Thus, early detection of cancerous tissue in the breast is critical.

Most of the characteristics of breast cancer do not differ significantly among women of different ages. Tumor types, for instance, are similar in older and younger women. (About 70 percent of all breast tumors are infiltrating ductal tumors, the most aggressive tumor type). Furthermore, tumor size may not be different in women of different ages. In a series of elderly patients treated for breast cancer at Memorial Sloan-Kettering, the size of the primary tumor ranged from 0.2 cm to 8.0 cm (0.8 to 3.6 in.) But no comparative data is available on tumor size in younger patients.

Of greater importance than tumor type, size, or location for all age groups, however, is the extent of disease at time of diagnosis, and this factor does show an age difference: elderly women have more advanced disease when cancer is detected. According to a recent report from Allen et al., older patients are 50 percent more likely than younger patients to have distant metastasis (that is, breast cancer that has spread to the bones, liver, brain, or other sites) (Allen, Cox, Manton, et al., 1986). In addition, patients older than 75 had an increased frequency of underarm lymph

node or chest wall involvement. The advanced disease at time of diagnosis observed in elderly women is probably due to diagnostic delay and not to a more aggressive type of tumor (Schottenfeld, et al., 1971).

Initial detection of breast cancer is usually a patient's discovery of a lump in the breast. However, older women discover their lesions far less often than younger women. In fact, if an older woman has a cancerous lump, there is only a 21 percent chance she will find it (Baker, 1982). Examination by a health professional may be a more sensitive test for the older woman detecting breast cancer (Fletcher, et al., 1985).

If a breast mass is discovered, the means of diagnosis will vary according to age of the patients and characteristics of the lesion. In younger patients, some practitioners will aspirate a breast mass that appears to be cyst rather than a tumor. However, the incidence of breast cancer is much higher in older women, so the breast mass is less likely to be cystic, and an initial needle aspiration is not done instead mammography is usually indicated. Some surgeons suggest immediate biopsy without the delay caused by mammography (Haagenson, 1987); however, mammography can indicate whether a lesion is localized, can detect lesions in the other breast that may have been undetected during the clinical examination, and can direct the surgeon to biopsy other areas.

Three procedures are employed for diagnosis: 1) excisional biopsy, 2) incisional biopsy, and 3) aspiration biopsy. Excisional biopsy involves removal of the entire tumor and often a margin of uninvolved tissue and is performed for lesions smaller than 2 cm. This is useful for patients who will undergo primary radiation treatment. Incisional biopsy is a sampling of a portion of the lesion, approximately 5 mm (0.2 in.) by 10 mm (0.4 in.); this procedure allows a smaller incision.

After either type of biopsy, a tumor section is than frozen and

analyzed. Immediate diagnosis is usually possible, although some less common forms of breast cancer may require at least 24 hours for a definitive diagnosis. Both of these procedures are performed in hospital or a free-standing ambulatory surgery center. The third procedure, aspiration biopsy, uses a large-bore needle to withdraw cellular material from the tumor. Although less accurate than an incisional or excisional biopsy, it can be performed in an office, under local anesthesia. Increased experience in cytologic analysis will probably improve the sensitivity of this technique.

When the above diagnostic studies are positive for breast cancer, pretreatment evaluation includes a complete history and physical examination by a physician. If a patient has symptoms or signs on physical examination that suggest that the disease has spread, extensive pretreatment evaluation may be necessary. For example, if examination reveals an enlarged liver, a liver-spleen scan or abdominal CT scan is indicated to document the presence of metastatic disease. If initial evaluation shows a breast cancer tumor that is either larger than 5 cm (2 in.), has extensive lymph node involvement, or is attached to the chest wall, the likelihood of metastasis to the bones merits the use of bone scans. At present time, however, there is little justification for routine pretreatment scans of the bones, liver, or head.

## Staging and Initial Treatment of Breast Cancer

For purposes of treatment and research, the concept of clinical staging or defining stages of disease has evolved (Sabiston, 1986). There are three methods in use for breast cancer, but the TNM (tumor, nodes, metastases) system (shown in Box A) has achieved the widest acceptance.

Briefly, Stage 0--carcinoma in situ--is the least severe, because it involves the smallest tumor and the cancer has not spread to any other site in the body (including axillary, or underarm, lymph nodes). Stage I disease

## Box A--Breast Cancer Staging

*T* (Primary Tumor)

- TIS: Preinvasive carcinoma (carcinoma in situ)
- TO: No demonstrable tumor in the breast
- T1: Tumor of 2 cm (0.8 in.) or smaller; skin not involved or involved locally in Paget's disease
- T2: Tumor 2 to 5cm (2 in.) in size
- T3: Tumor greater than 5 cm. (2 in.) in size
- T4: Tumor of any size with any of the following: skin infiltration, ulceration, peau d' orange, skin edema, pectoral muscle or chest wall attachment

N *(Regional Lymph Nodes)*

- NO: No clinically palpable axillary, or underarm, lymph nodes
- N1: Clinically palpable but movable axillary nodes (N1a-mestastasis not suspected, N1b-metastasis suspected)
- N2: Clinically palpable, fixed, axillary nodes (metastasis suspected)
- N3: Homolateral supra or infraclavicular nodes considered to contain metastasis; edema of the arm.

M *(Distant Metastasis)*

- MO: No distant metastasis
- M1: Clinical and radiographic evidence of metastasis except those to homolateral axillary or infraclavicular lymph nodes; includes skin involvement beyond the breast

*Stages*

Stage I: T1, NO, or N1a, MO
Stage II: T1, N1b, MO; T2, NO, MO; or TO, N1b, MO; T2, N1a, MO; or T2, N1b, MO
Stage III: Any T3 with any N, MO
Any T4 with any N, MO
Any T with N2 or N3, MO
Stage IV: Any T, any N with M1

involves a small tumor (2 cm [0.8 in.] or smaller), no or very few axillary lymph nodes affected, and no distant metastases. Stage II is defined in a variety of ways, involving combinations of tumor size and axillary lymph node involvement, but no distant metastasis; most typically, Stage II breast cancer involves large tumors and little node involvement, or small tumors and extensive, but movable, lymph nodes. Stage III disease involves either a very large tumor (more than 5 cm) with any axillary lymph node involvement, or any size tumor with fixed lymph node involvement, but again no metastatic disease. Metastatic disease is the defining characteristic of Stage IV breast cancer.

Breast cancer spreads directly to the chest wall, locally to the lymph nodes and distantly to other organs, primarily the lungs, the liver, and the bones. Ultimately, any organ can be affected by a breast tumor. The extent of axillary (underarm) lymph node involvement is important, because the cancer is much more difficult to contain once it has entered the lymph system. The five-year relapse rate of patients with one to three cancerous nodes is approximately 50 percent, but with 4 or more positive nodes it is almost 80 percent, even with treatment. Estrogen receptors, which are assayed by laboratory analysis on the primary tumor, are also important to prognosis. Positive estrogen receptors, that is, cancer cells that still respond to hormones, are often found in post-menopausal women and are associated with well-differentiated and more favorable disease outcome.

Several forms of therapy are availabe for the management of primary breast cancer, depending on such factors as stage at diagnosis, size of tumor, and patient preference (e.g. NCI, 1987). Surgical treatment is still the cornerstone of therapy for Stages I through III in elderly patients. The various surgical procedures include the following: (1) extended radical mastectomy, (2) radical mastectomy, (3) modified radical mastectomy, (4) total mastectomy, and (5) partial mastectomy or wide local excision. These five

procedures differ in the amount of tissue removed and in whether the regional lymph nodes or chest wall musculature are removed. Extended radical mastectomy and radical mastectomy will not be discussed in this report because they are seldom performed on elderly patients and are currently out of favor as treatments for patients of all ages. The third procedure, modified radical mastectomy, involves removal of the breast, underarm nodes, and sometimes the chest muscle under lying the breast. This is the most common treatment, and may be used in Stages I, II, or III. The fourth procedure, total mastectomy, removes the entire breast and the tissue that extends from the breast to the underarm, but it leaves the lymph nodes. This procedure is used for Stage I breast cancer and occasionally in Stage III in conjunction with other types of therapy. Finally, partial mastectomy, or "lumpectomy," removes only the tumor and 1-2 cm (0.4 to 0.8 in.) of surrounding normal tissue. It is used in Stage I breast cancer, in which it is followed up with radiation therapy, or occasionally in more advanced stages to remove an ulcerated tumor, followed up with chemotherapy.

An important adjunct to surgery is axillary node dissection, in which the contents of the underarm are exposed and some lymph nodes are removed to test for the presence of cancer cells. If cancer cells are present, it indicates the possibility that cancer has spread to other regions of the body, although it may not have affected other organs. Dissection is indicated for all patients with palpable lymph nodes and those who are to be treated with primary radiation therapy. The dissection needs to be extensive enough to detect any metastases without running a risk of functional or cosmetic deformity (Harris, Hellman & Kinne, 1985). Nevertheless, dissection causes some patients to experience continued functional impairment and/or permanent obvious swelling.

Radiation therapy may also be used to treat breast cancer. It is

typical in several circumstances: as a primary treatment for patients in Stage I or II; in conjunction with chemotherapy for Stage III disease; after a partial mastectomy and axillary node dissection; or as a palliative (non-curative) treatment for patients with recurrent chest-wall disease or bone or brain metastases. When radiation treatment is a primary treatment, patients receive external beam radiation to the breast and underarm and an implant of a radioactive isotope to maximize local tumor control. Primary radiation therapy is still under evaluation as an alternative to mastectomy, and information is not yet available on the experience of older women with this treatment (Fisher, et al., 1985). However, this therapy may be recommended for older women who are poor risks for surgery.

Chemotherapy is the third major form of treatment for breast cancer. However, chemotherapy, like radiation, causes side effects that can lead to considerable distress and additional illness. The harmfulness of various chemotherapeutic agents varies with the dose and the patient. Finding the best drug combination continues to be the subject of clinical investigation (USDHHS, NCI, 1987). One hormone therapy taken orally, tamoxifen, is perhaps the least discomforting of agents, causing mild hot flashes. Tamoxifen is commonly prescribed for postmenopausal women, usually alone but sometimes in conjunction with other chemotherapeutic agents. It is used for a two-year period, provided that there is no further cancer spread.

Nonhormonal therapy for breast cancer also exists. A typical nonhormonal chemotherapeutic regimen is CMF, a combination of cyclophosphamide, methotrexate, and 5-fluorouracil (5-FU), given for six months. Typical side effects of CMF include mouth sores; nausea; vomiting; diarrhea; hair loss; bone marrow suppression, especially of the infection-fighting white cells; and, occasionally, hemorrhagic cystitis (bloody urine). In younger women, CMF can cause suppression of menstruation and premature

menopause. Other nonhormonal agents exist, but also carry side effects. Adriamycin, a drug mainly used in advanced (Stage III or IV) cases of breast cancer, has been found to be damaging to the heart. As a consequence, monitoring scans of the heart are required, using up additional health care resources and thus additional costs. Vinblastine, another chemotherapeutic agent used for breast cancer, causes bone marrow suppression of all blood counts. A typical outpatient regimen is CMF therapy, requiring two intravenous infusions of methotrexate and 5-FU per month, and cyclophosphamide taken orally each day. Vinblastine may be given intravenously, but it must be continuous over a five-day period and requires hospitalization.

## Continuing Medical Problems of Women with Breast Cancer

As noted earlier, current estimates are that 50 percent of women with little or no lymph node involvement, and 80 percent of women with involvement of four or more nodes, relapse within 5 years of initial treatment. The common sites of involvement in metastatic disease are bones, lungs and pleura (lung lining), and liver.

Breast cancer metastasizes to the bone more commonly than do other cancers; metastases to the bones occur in approximately 50 percent of patients with metastatic breast cancer. Metastasis may involve either the axial skeleton (skull, ribs, spine and sacrum) or the appendicular skeleton (long bones). Axial metastasis may threaten neurologic function and cause great pain by impinging on the spinal cord, brain, or nerves. Appendicular metastasis that may threaten stability of the long bones and create a pathologic fracture that requires surgical implantation of various rods in the limbs. The main treatments, usually palliative, for bony metastases are radiation therapy, hormonal therapy, or chemotherapy, in addition to orthopedic stabilization. Patients with bony metastases also suffer from

considerable secondary illness, pain, and loss of mobility. For the older woman, the impact of these problems can be particularly devastating because the patient usually becomes completely dependent and may need to be placed in a nursing home if the family is unable to provide care in the home. Another complication that may arise is hypercalcemia (excess calcium in the blood); this is usually life-threatening, occurs in the setting of extensive bone disease, and may require weekly treatment.

Lung and pleural metastasis is also very common in women with breast cancer. Breast disease in the lungs can cause severe shortness of breath, coughing, and accumulation of fluid in the lining of the lungs. If the lungs are involved, chemotherapy is the usual form of treatment; patients with advanced disease may also require home oxygen use. Fluid in the lining of the lungs requires frequent aspirations and sclerosing of the tissue (scarring the tissue so that it cannot make fluid anymore) to provide symptomatic relief.

Liver metastases in patients with breast cancer usually cause death within six months. Treatment is usually radiation or chemotherapy or sometimes a combination of the two. Treatment offers little hope of increased survival to most patients but can relieve pain. Other sites may be involved in metastatic breast cancer, but they are less common. Central nervous system (CNS) involvement includes metastasis to the brain, the spinal cord, and the peripheral nerves. Patients with CNS involvement may suffer loss of brain or spinal cord function with subsequent paraplegia. The complications of this form of metastatic disease are treated with radiation therapy or palliative neurosurgical procedures, such as cutting pain fibers or removing tumors from the spinal cord.

The complications described above are representative of the numerous medical problems requiring extensive medical management that arise in patients with advanced breast cancer. The economic impact of metastatic breast cancer in

elderly women, like the effects on these women's health, is enormous.

## PART III: EFFECTIVENESS AND COSTS TO MEDICARE OF BREAST CANCER SCREENING FOR WOMEN 65 AND OLDER

### INTRODUCTION

Several studies have shown that screening for breast cancer can decrease morbidity and mortality from this disease, indicating it might be appropriate to cover breast cancer screening for the Medicare population. This section estimates the effectiveness, risks and costs of screening women over the age of 65 for breast cancer.

### Evidence of Effectiveness

Five controlled trials and one uncontrolled study provide information on the reduction in mortality achieved by screening women over age 65 for breast cancer. The main features of the studies are summarized in Table 6. In addition, controlled studies now in progress in the United Kingdom, Canada, and Sweden are expected to contribute to our understanding of the effectiveness of breast cancer screening.

#### New York (HIP) Study

Beginning in December 1963, the Health Insurance Plan (HIP) of Greater New York conducted a randomized controlled trial involving approximately 62,000 women ages 40 to 65. One group of about 31,000 women (the study group) was offered four successive annual examinations with mammograms (two views) and breast physical examinations. About 67 percent of the women offered the examinations accepted, about 57 percent of those offered screening received two or more examinations, and about 50 percent received three or more examinations. The study showed a statistically significant reduction in mortality in women who were older than 50 when they entered the study (Table 5). Within five years after entry, breast cancer mortality was reduced about

TABLE 5

HIP RESULTS FOR WOMEN AGE 50 TO 65 AT ENTRY

CUMULATIVE NUMBER OF BREAST CANCER DEATHS

Years After Entry

| | 5 yrs | 10 yrs | 14 yrs | 16 yrs | 18 yrs |
|---|---|---|---|---|---|
| Study group | 20 | 56 | 72 | 72 | 77 |
| Control group | 43 | 82 | 92 | 94 | 98 |

TABLE 6

DESCRIPTIONS OF SIX STUDIES
OF BREAST CANCER SCREENING EFFECTIVENESS

| Trial | Design | Dates of Screening | Ages* | Screening: Mammogram | Screening: BPE | Screening: Frequency | Compliance | Reduction in Mortality (%): 5 yrs** | 5-10 yrs | 10 yrs | 18 yrs |
|---|---|---|---|---|---|---|---|---|---|---|---|
| HIP (USA) | RCT | 1963-67 | 50-65 | 2-view | yes | 12 mos. | ~ 50% | 50% | - | 32% | 21% |
| Sweden | RCT | 1977- | 60-69<br>70-74 | 1-view | no | 20-36 mos. | ~ 80% | - | 38%<br>15% | | |
| Nijmegen (The Netherlands) | case control | 1975- | 50-64 | 1-view | no | 24 mos. | 100% | - | 52% | | |
| | case-control | 1975- | 65+ | 1-view | no | 24 mos. | 100% | - | 19% | | |
| DOM (The Netherlands) | case-control | 1975- | 50-64 | 2-view | yes | 12-24 mos. | 100% | - | 70% | | |
| Florence (Italy) | case-control | 1979- | 50-70 | 2-view | no*** | 30 mos. | 100% | - | 76% | | |
| BCDDP (USA) | uncontrolled | 1973-81 | 50-74 | 2-view | yes | 12 mos. | 100%**** | | 58%***** | | |

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* "Ages" refers to the ages at entry of the women on whom the results reported in this Table are based. Individual trials might have screened women in other age groups. The results for those women are not reported here.

** years after invitation to be screened

*** Breast physical examination and other tests performed "in selected cases."

**** Estimated reduction in mortality applies to cases detected through screening

***** comparison with national statistics (SEER)

53 percent in those offered screening versus controls. As follow-up time increased, the reduction in mortality decreased: about 32 percent after 10 years, and about 22 percent after 18 years. After 18 years, the degree of reduction was slightly lower for women ages 60 to 64 at entry than for women ages 50 to 59 at entry (Shapiro, et al., 1985).

Swedish Study

An ongoing randomized controlled trial begun in Sweden in 1977 is evaluating the effectiveness of single-view (oblique) mammography (with no breast physical examinations) delivered every 20 to 36 months in women over age 39. Approximately 94,000 women in two counties were offered mammography screening. Their results will be compared with a control group of approximately 67,000 women who are the same ages and from the same two counties. The screening and control groups were selected with a cluster-sampling technique using communities as the random unit. In the group offered screening, 23,799 were ages 60 to 69 at entry, 16,305 were ages 70 to 74 at entry, and 16,305 were over age 75 at entry. In the control group, the numbers of women in the three age groups were 16,594, 7462, and 11,809, respectively. Among women ages 60 to 69, the acceptance rate was about 88 percent for the first examination and 81 percent for the second examination. In women 70 to 74, the acceptance rate was 79 percent for the first examination and 67 percent for the second. Among women older than 75, the acceptance rate was 52 percent for the first examination (Tabar, et al., 1985a).

The effect on mortality in women offered screening has been published for women ages 40 to 74. The results in women ages 50 to 74 are the most pertinent for estimating the value of screening in women older than 65. Within 8 years after entry into the trial (Tabar, et al., 1985b), combining the results in the two counties, there were 71 breast cancer deaths in the

screening group (of a total of 58,148 women) and 76 breast cancer deaths in the control group (of a total of 41,104 women). This represents a reduction in mortality of 34 percent. The relative risk of dying of breast cancer in screened versus unscreened women was 0.61 (95 percent confidence interval, 0.44 to 0.84) (Tabar, et al., 1985b). Mortality results broken down by age (50-59, 60-69 and 70-74) have been calculated (Miller 1987). They indicate that the effect on mortality from breast cancer causes is lower in women ages 60-69 than ages 50-59, and even lower in women ages 70-74. Results have not been reported for women over age 75.

The Dom Project

A case-control study was used to evaluate a screening program begun in 1975 in Utrecht, The Netherlands for women ages 50 to 64. The screening involved two-view mammography and breast physical examinations, conducted at 12, 18 and 24 months. The results indicate that screening reduced the risk of dying from breast cancer, with a relative risk of 0.30 (95% confidence interval, 0.13 to 0.7) (Collette, et al., 1984), or about a 70 percent reduction in probability of dying of breast cancer. Although this study was limited to women younger than 65, the effect of screening was observed to increase with age, which suggests that screening would be effective in older women.

Nijmegen (The Netherlands) Study

Another screening program was introduced in The Netherlands in 1975, involving single-view mammography every two years (no breast physical examinations) for women ages 35 to 65. After seven years of screening, the results were evaluated using a case-control design; 62 women who died of breast cancer were matched with 310 controls (with the same year of birth). This study indicated that screening decreased breast cancer mortality in women older than 50, with a relative risk of breast cancer death in ever-screened

versus never-screened women of 0.48 (95 percent confidence interval, 0.23 to 1.00). This implies a mortality reduction of approximately 50 percent. For women over age 65, the relative risk was 0.81 (95 percent confidence interval, 0.23 to 2.75) (Verbeek, et al., 1985), implying a mortality reduction of approximately 20 percent. Thus, the observed effect on women older than 65 was not as great as on women ages 50 to 65 and, due to the small number of cases in this age group (16 breast cancer deaths), there is a wide range of uncertainty.

Florence

Another case-control study conducted near Florence involved a breast cancer screening program begun in 1979 that consisted of two-view mammography every 2.5 years for women between ages 40 and 70 (Palli, et al., 1986). Breast physical examinations and other tests were performed "in selected cases." Each of 57 cases was matched with five controls by year of birth and place of residence. The median interval between invitation to be screened and death was seven years. The odds ratio of dying of breast cancer among "screened" women compared with "never screened" women was 0.53 (95 percent confidence interval, 0.29 to 0.95), which implies a 47 percent reduction in mortality. For women older than 50 at diagnosis, the odds ratio for women with at least two screening examinations, compared with "never screened" women, was estimated to be 0.24 (95 percent confidence interval, 0.13 to 0.43). This implies a mortality reduction of approximately 75 percent. Results have not been reported separately for women older than 65.

Breast Cancer Detection Demonstration Project (BCDDP)

The BCDDP screened more than 280,000 women with a combination of mammography and breast physical examination (plus thermography for some cases) between 1973 and 1981 (Baker 1982). About half were over age 50 at entry into the study. Although the study was uncontrolled, its results have been compared with national statistics from the SEER data base (Seidman, et al., 1987). For women over 50 with breast cancer diagnosed through screening in the BCDDP, relative five-year survival was 89%. Relative five-year survival for women over 50 in the SEER program was 74%. If taken at face value this implies more than a 50% reduction in mortality at five years.

Estimated Effectiveness of Breast Cancer Screening in Women Older Than 65

The available evidence documents that screening women from ages 50 to 65 reduces breast cancer mortality, and strongly suggests that screening women older than 65 will also reduce breast cancer mortality. A more difficult question is the expected magnitude of the reduction in mortality. We sought to estimate this magnitude for women older than 65 in the United States who accept screening with annual breast physical examinations and mammography (the "target program"). Unfortunately, none of the controlled studies focuses specifically on these questions, and as a consequence there is considerable uncertainty about the actual impact such programs would have. As shown in Table 5, the existing studies involve a number of different factors: countries, designs, time periods, age groups, screening protocols, compliance rates, and followup times. Each of these factors might bias the results of the studies as estimates of the effectiveness of the target program.

Country. The six studies involve four different countries, with different breast cancer epidemiologies, patient behaviors, practitioner skills, and treatment patterns. Any of these factors could cause the observed results to be different from those of the target program.

Research Design. The studies differ in their designs, in the nature of the screening programs being evaluated, and in the sample sizes. In studies that use a case-control design (DOM, Nijmegen and Florence), the investigators attempt to match controls with cases according to potential confounding factors. However, with such a design, the matching can never be as effective as using random allocation (HIP and Sweden), and biases can exist. The study that offers the closest match to the target program is the BCDDP, yet this was uncontrolled. Its results have been compared with national statistics, but it is impossible to rule out biases that plague uncontrolled studies. For example, the women who sought screening in the BCDDP could be more likely to detect their cancers earlier than average, which would cause a comparison with national statistics to overestimate the effectiveness of screening. With respect to the nature of the screening programs, the case-control studies in The Netherlands and Italy retrospectively evaluated community-based screening programs that were "natural," that is, their primary purpose was to screen women, not to evaluate the effectiveness of screening. We can expect their results to represent fairly well the effectiveness of similar community-based programs. Yet a randomized controlled trial that is designed, funded and conducted prospectively for the primary purpose of evaluating the effectiveness of screening might involve special efforts to achieve the highest possible quality of screening. Such special efforts might bias upward the effectiveness of screening that could be expected to occur in more natural settings. Finally, the different sizes of the studies can affect the confidence limits of their results.

Time Period. The New York (HIP) study was conducted in the late 1960s. Since then, mammography techniques have improved, which might translate into greater reductions in mortality. The quality of mammography has also improved since the other studies were begun in the late 1970s, but to a lesser extent.

Age Group Screened. Most of the studies examined women older than 50 at entry, but not older than 65. Evidence from the Nijmegen, The Netherlands study suggests that mammography might be more effective in women between ages 50 and 65 than in women older than 65. Furthermore, in the New York (HIP) and Swedish studies, mammography appeared to be less effective in women ages 56 to 65 than in women age 50 to 60, and even less so for women age 70 to 74 in the Swedish study, which might indicate a trend toward even lower mortality reductions for women older than 65.

Screening Protocols. If all else is equal, the following assumptions can be made: two-view mammography should be more effective in reducing mortality than single-view mammography, mammography with breast physical examination should be more effective than that without a breast physical examination, and frequent screening should be more effective than infrequent screening. Thus, the facts that the Swedish study involved single-view mammography, delivered every 20-36 months, and did not include a breast physical examination, should cause that study's results to underestimate the effectiveness of the target program (two-view mammography, coupled with breast physical examinations, delivered every 12 months).

Compliance. The fact that not all women offered screening in the HIP study accepted it tends to cause the results of this study to underestimate the effectiveness of screening for women who do accept it. Incomplete compliance also affects the results from Sweden, although to a lesser extent. Because the case-control designs of the Netherlands and Italian studies estimate the effectiveness of screening only for women who are screened, they are not affected by this bias.

Follow-up. Evidence from the New York (HIP) study indicates that the reduction in mortality achieved by screening might not be constant over time. In women ages 50 to 65, the reduction in mortality slowly decreased: there

was a 50 percent reduction at 5 years after entry but only a 20 percent reduction at 18 years after entry. The other studies have not had sufficiently long follow-up periods to address this question.

Net Effect. In any given study, the factors just discussed can have conflicting effects. For example, in the New York (HIP) study, the prospective design and younger age group would tend to bias the effectiveness of screening observed in the study upward compared with the target program; whereas, the incomplete compliance and subsequent technical improvements in mammography tend to yield results that underestimate the effectiveness of the target program. In the Swedish study, the inclusion of women younger than 65 in the reported results might bias the effectiveness of screening upward; however, the lack of a breast physical examination, the longer intervals between examinations, and the incomplete compliance all tend to give results that underestimate the effectiveness of the target program.

Baseline Assumption. There are no empirical data from which to calculate the net effect of all these biases. For this analysis, we will use a baseline assumption, based loosely on the results of the New York (HIP) study and the BCDDP: screening women over age 65 in the United States with annual breast physical examinations and annual mammograms will reduce mortality in women who accept screening by approximately 50 percent after five years, gradually decreasing to approximately 40 percent after 10 years and approximately 30 percent after 20 years. The impacts of other assumptions and of biennial mammography will be discussed. It should be stressed that because none of the research studies matches the target program precisely, there is considerable uncertainty about the actual effectiveness of screening in reducing mortality. The baseline assumption is one estimate made to indicate the approximate magnitude of the effect. A method for exploring the impact of other assumptions will be described.

To calculate the cost-effectiveness of screening, estimates must be made of how screening will change the proportion of women with breast cancer detected in various stages. For women older than 65 who are not screened, the proportions are as follows: stage 0, 0.051; stage I, 0.248; stage II, 0.534; stage III, 0.081; and stage IV, 0.086 (Surveillance and Operations Research Branch, Division of Cancer Prevention and Control, National Cancer Institute [NCI]).[14] However, there are no data from controlled trials on how screening changes the proportion of cancers detected in each stage, for women over age 65. For this analysis a shift in stage was chosen to achieve the assumed reduction in mortality at each followup period. The stage proportions used in the base case analysis were: stage 0, 0.05; stage I, 0.4; stage II, 0.55; stage III, 0; and stage IV, 0. It should be stressed that these stage proportions are not empirically based, but are chosen to achieve the reduction in mortality assumed in the base case. These proportions affect the estimated savings in initial treatment costs (which depend on the assumed shift in stage proportions). To estimate the reduction in number of late-stage cancers, an indicator of morbidity, the stage proportions observed in the BCDDP will be compared with the stage proportions in SEER. The implications of using different stage proportions will be described.

## RISKS

### Radiation Hazard

While there is good evidence that high doses of radiation can cause breast cancer in younger women, the carcinogenic effect of modern mammography for women over age 65 is negligible. First, the usual dose used for mammography is very low (reported in 1986 to range from about 60 to 350 millirads, depending on the technique [Skubic and Fatouros, 1986; also see National Committee on Radiation Protection and Measurements, 1986]). Second,

the carcinogenic effect of the radiation in women over age 65 is virtually nil -- increasing the incidence rate by a factor of less than 0.001 (excess risk). Ten examinations from age 65 through 74 might be expected to cause less than five new breast cancers in one million 65-year-old women over the remainder of their lifetimes (calculated from results in Gohagan, et al., 1986). This can be compared with about 48,600 "natural" cases of breast cancer in the same population over their lifetimes (see below).

Surgery Recommendations

An additional consequence of screening is that both breast physical examinations and mammograms can detect lesions that are not in fact breast cancers, but that warrant surgical consultations and sometimes breast biopsies for confirmation. In the BCDDP, at any particular examination the false-positive rate of the combination of mammography and breast physical examination (defined as the probability that a woman who does not actually have breast cancer will have a breast physical or mammographic examination result positive or suspicious enough to warrant a recommendation for diagnosis, aspiration, or surgical consultation) was approximately 2% (Baker 1982). In the absence of screening, some of these women might have sought care, implying that the increase in probability of a surgical consultation for a false-positive examination will be less than 2%.

## Costs

This analysis will estimate how breast cancer screening will affect actual medical care costs paid by Medicare. In focusing on these costs, it should be stressed that there are additional medical care costs that are not paid by Medicare but by other third-party payers such as Medicaid and private insurers, or by individual women. Furthermore, breast cancer and breast cancer screening affect other costs not directly related to medical care. For

example, a woman who has breast cancer, or her family, can suffer financial losses due to lost time from work, transportation, home help, and so forth. Many women age 65 and over are still in the work force, many do volunteer work, and many help their working adult children. Finally, there are nonfinancial costs of breast cancer that might be affected by screening. These were discussed in the section on "medical issues" (Part II of this staff paper).

The cost of breast cancer screening to the Medicare program includes the costs of the screening examinations, workups of patients with positive screening tests, initial treatment, continuing care, terminal care for women who die of breast cancer, and terminal care for women who die of other causes. All estimates of costs will be in 1984 dollars.

Screening Examinations

Charges for mammography range from $25 to more than $200. The average charge in 1982 for the screening centers that followed the BCDDP was $100 (Baker 1984). However, many centers have shown that screening mammography can be profitably offered for $35 to $45 (see the section on "resources"). Charges for a breast physical examination also vary widely. While charges to Medicare for physician visits indicate that Medicare could be charged as much as $30 for a screening breast physical examination (USDHHS, BMAD, 1987a), it is conceivable that if done in conjunction with screening mammography, a screening breast physical examination could be much less expensive. This analysis will use a baseline assumption that Medicare will pay $50 (1984 dollars) for a combination of screening mammography and screening breast physical examination. The implications of a $70 cost (1984 dollars) will also be presented.

Workups

Charges submitted to Medicare for a workup will vary depending on the

nature of the workup (e.g., needle biopsy versus excisional biopsy) and the setting (e.g., inpatient versus outpatient). Charges in 1984 ranged from about $700 to more than $3000 (USDHHS, BMAD, 1987a). Based on Medicare data, this analysis will assume that the average cost to Medicare of a workup will be $900 (1984 dollars). This is estimated from the weighted average of the costs to Medicare of possible additional confirmatory mammograms, biopsies, and associated doctor visits (see Appendix A).

## Treatment Costs

The cost to Medicare of treating breast cancer has been estimated from the Continuous Medicare History Sample File (CMHSF) by the Surveillance and Operations Research Branch, Division of Cancer Prevention and Control, NCI (cf. Baker, Kessler & Smucker, 1987; Baker, Kessler & Smucker, in preparation) (Charges to Medicare for breast cancer based on the CMHSF file are shown in Appendix B in this staff paper). Unless otherwise noted, all the cost estimates in this section are based on that analysis.

Initial Treatment. The average cost to Medicare for initial treatment for breast cancer (treatment within the first three months after diagnosis) was $5,291 (1984 dollars).[15] Because some components of initial treatment such as chemotherapy and radiation therapy require more than three months, this cost might underestimate the true cost to Medicare, but the effect should be relatively small, and should have a negligible impact on the estimated net costs associated with screening (see section on "sensitivity analysis"). To estimate the potential savings in treatment costs due to detecting cancers in earlier stages, it is necessary to estimate the cost of initial treatment for each stage. Unfortunately, there are no Medicare data on cost per stage. For this analysis, the approximate costs of initial treatment by stage were calculated as follows. For each stage, the proportion of Medicare patients

receiving various types of treatment (e.g., simple mastectomy, modified radical mastectomy, simple mastectomy plus radiation) were determined from Medicare files. These proportions were then multiplied by the average charges submitted to Medicare Part A (inpatient) for each type of treatment (estimated by OTA staff and consultants), to obtain a figure for the average inpatient charge for each stage. (These charges were as follows: stage 0, $4144; stage I, $4383; stage II, $4584; stage III, $4882; and stage IV, $5116.) These figures were then multiplied by a factor (1.155) calculated to cause the weighted average of costs for all stages to match the average cost for all stages obtained from more current Medicare files and to include outpatient charges (USDHHS, HCFA, 1987a, 1987b). This approach led to the following estimated costs to Medicare for initial treatment for each stage: stage 0, $4786; stage I, $5062; stage II, $5295; stage III, $5639; and stage IV, $5909.

Continuing Care

Medicare data indicate that the cancer-specific cost to Medicare of continuing care for a woman with breast cancer is approximately $183 per month.[16] There are no data on continuing care costs as a function of stage. To the extent that continuing care costs are lower for women with cancer diagnosed in earlier stages, failure to incorporate stage-specific continuing care costs might overstate the net financial cost due to screening. The possible effect of this on the net cost of screening will be discussed below (see section on "sensitivity analysis").

Terminal Care

Terminal Care for Breast Cancer. The cancer-specific cost to Medicare of terminal care (defined as care delivered during the last six months of life) for patients dying of breast cancer is $10,776 (see Appendix B).

Terminal Care for Other Causes of Death. The cost to Medicare of terminal care (last six months of life) for all causes of death averages $7618

(see Appendix B).

## Calculation Methods

A mathematical model was used to estimate the impact of breast cancer screening on morbidity and mortality as well as on financial costs, for an individual woman and for the Medicare population (Eddy 1986). The mathematical model consists of five submodels. A population submodel starts with the U.S. population in 1980 (including the distribution by sex and five-year age groups), and uses estimates of future birth and death rates to estimate the number of people in the U.S. population for each year in the future, by sex and five-year age group. A cancer incidence submodel uses information on age- and sex-specific cancer incidence rates to estimate the number of new primary cases of cancer that will occur in each year in the future. This submodel accepts information on risk factors to estimate the number of cancer cases for different risk groups. A disease submodel uses data on the proportion of cancers detected in each stage, and on stage-specific relative survival rates, to estimate the probability that a cancer patient will die of cancer, for each year after the diagnosis. The effect of screening on cancer mortality is calculated by changing the proportion of cancers detected in each stage, to reflect the fact that screening tends to find cancers in earlier stages, and (optionally) by altering stage-specific relative survival rates. A fourth submodel keeps track of the probabilities that both cancer patients and people without cancer will die of other causes. Finally, a cost submodel keeps track of the costs of screening, workups, initial treatment, continuing care, terminal care for patients dying of cancer, and terminal care for people (with or without cancer) dying of other causes.

Together, these submodels simulate what would actually happen if a

screening program were introduced in a population, keeping track for each future year of such outcomes as how many women are eligible for screening, how many are diagnosed as having breast cancer (by stage), how many carry the diagnosis of breast cancer, and how many die of breast cancer or other causes. It also calculates the financial costs associated with all the important events (e.g., screening, workups, treatment).

The model performs its calculations in yearly cycles. To estimate the effects of a breast cancer screening program for women over age 65, each year the population submodel calculates the number of women in the United States in the designated age group (e.g., 65 through 74) who do not yet have a diagnosis of breast cancer and who are candidates for screening. For the years in which screening is to be performed (e.g., 1987 to 2020), and for the proportion of women in the designated age group who actually are screened (e.g., 30 percent), the disease submodel calculates the number of women screened and the number of women who will be diagnosed in each cancer stage, both with and without the screening activity. From this information on the proportion of women diagnosed in each stage with and without screening, as well as from any information on changes in stage-specific relative survival rates, the submodel calculates for each year how screening changes the number of women who will die of breast cancer, or from other causes. For each year, the disease submodel also calculates now many women will have false-positive examinations, how many will receive initial treatment (by stage), how many will require continuing care for breast cancer (by stage), how many will die of breast cancer, and how many will die of other causes. The latter information is used by the cost submodel to calculate the costs and savings associated with each of these events, as well as the net costs, for each year.

To execute the model, in addition to the assumptions already described, data are required for the age distribution of the population, projected birth

rates, age-specific breast cancer incidence rates, age-specific mortality from breast cancer, age-specific mortality from other causes of death, and survival rates by stage. These were drawn from standard sources described in Levin et al., (1986).

## Cost-effectiveness of Breast Cancer Screening

Given the assumptions described earlier (Table 7), the effect of breast cancer screening can be estimated. The results will depend on the age group screened. The first two sets of results give the effects of screening women with annual breast physical examination and mammography, from ages 65 through 74, from the perspective of an individual woman and from the perspective of Medicare (Tables 8 and 9). Additional results for other age groups and for biennial screening will be given from the perspective of Medicare (Tables 10 through 15).

### Effect on Individual Woman

Table 8 summarizes the impacts of breast cancer and of being screened from ages 65 through 74 from the perspective of a 65-year-old average-risk woman.[17] A woman at age 65 has about a one in 20 chance (520 in 10,000) of developing breast cancer some time in the rest of her life. The probability of developing breast cancer in the coming year is approximately one in 386 (25 in 10,000). If the woman is not screened, her chance of dying of breast cancer that occurs at age 65 or later is approximately one in 67 (149 in 10,000). If she is screened for 10 years (from ages 65 through 74), her chance of dying of a breast cancer that occurs at age 65 or later is approximately one in 83 (121 in 10,000). Thus screening will make the difference between life and death from breast cancer for 28 in 10,000 women screened. If the woman does develop breast cancer, in the absence of screening her chance of dying from it is approximately 28.6 percent. With

TABLE 7

SUMMARY OF BASELINE ASSUMPTIONS

1. Screening includes annual breast physical examination and mammography.

2. 30% of women offered screening will accept.

3. The group of women who accept screening together have an average risk of developing breast cancer.

4. Screening reduces mortality by 50% at five years, gradually decreasing to 30% at 20 years.

5. The combined false-positive rate of the two examinations is 2%.

6. Costs to Medicare:

| | |
|---|---|
| Screening mammogram and breast physical examination | $ 50 |
| Workup | $ 900 |
| Initial treatment | |
| stage 0 | $ 4,786 |
| stage I | $ 5,062 |
| stage II | $ 5,295 |
| stage III | $ 5,639 |
| stage IV | $ 5,909 |
| Continuing care* (per month) | $ 183 |
| Terminal care - breast cancer | $10,776 |
| Terminal care - other causes | $ 7,618 |

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* difference between breast cancer and other causes o death

TABLE 8

THE BENEFITS AND RISKS OF 10 YEARS (FROM AGE 65 THROUGH 74)
OF ANNUAL BREAST PHYSICAL EXAMINATIONS AND MAMMOGRAMS
FOR AN ASYMPTOMATIC AVERAGE-RISK 65-YEAR-OLD WOMAN

| QUESTION | ANSWER* |
|---|---|
| 1. What is the chance a 65-year-old average-risk woman will be diagnosed as having breast cancer some time in the rest of her life? | 520 in 10,000 |
| 2. What is the chance she will be diagnosed with breast cancer some time in the coming year? | 25 in 10,000 |
| 3. What is the chance she will die of a breast cancer diagnosed after age 65, if she is <u>not</u> screened? | 149 in 10,000 |
| 4. What is the chance she will die of a breast cancer diagnosed after age 65 if she is screened for 10 years from age 65 to age 74? | 121 in 10,000 |
| 5. What is the difference in the chance of breast cancer death resulting from 10 years of mammography screening? | 28 in 10,000 |
| 6. If a woman is destined to get breast cancer after age 65, how much will 10 years of mammography screening (delivered at ages 65-74) reduce the chance she will die of it? | 19 percent |
| 7. How much will 10 years of mammography and breast physical examination add to the expected lifetime of a woman destined to get breast cancer after age 65? | 258 days |
| 8. How much will 10 years of mammography and breast physical examination add to the expected lifetime of an asymptomatic woman who might or might not ever get breast cancer (with 5.2% probability)? | 13.4 days |
| 9. What is the chance a single mammography examination will cause a breast cancer some time in the rest of her life? | less than 1 in 500,000 |
| 10. What is the chance a particular mammographic examination will be falsely positive leading to a recommendation for a biopsy? | 2 in 100 |
| 11. What is the chance of a late-stage cancer (stage II >5 cm or with positive nodes, stage III, or stage IV), if she is not screened? | 305 in 10,000 |
| 12. What is the chance of a late-stage cancer (stage II >5 cm or with positive nodes, stage III, or stage IV), if she is screened for 10 years? | 224 in 10,000 |
| 13. How much will 10 years of screening (ages 65-74) reduce the chance a woman will ever have a late-stage cancer (stage II >5 cm or with positive nodes, stage III or stage IV)? | 81 in 10,000 |

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*based on baseline assumptions (Table 3)

TABLE 9a

THE ANNUAL IMPACT ON MORTALITY AND MORBIDITY
OF SCREENING 30% OF ASYMPTOMATIC WOMEN IN THE U.S.
AGE 65 THROUGH 74
WITH ANNUAL BREAST PHYSICAL EXAMINATIONS AND MAMMOGRAPHY
1987 TO 2020

USES BASELINE ASSUMPTIONS

| Year | # Women 65-100 in the US (1) | # Cases (2) | Impact on Breast Cancer Deaths: Annual Impact No Screening (3) | With Screen (4) | Diff. (5) | Cumulative* # of Person-Years of Life Saved (6) | Impact on Breast Cancer Morbidity: Annual # of Late Stage** Cases Prevented*** (7) | Cumulative* # of Late Stage** Cases Prevented*** (8) |
|---|---|---|---|---|---|---|---|---|
| 1990 | 17,865,000 | 49461 | 21108 | 20537 | - 571 | 3421 | 2241 | 8925 |
| 1995 | 18,405,000 | 51297 | 22602 | 21835 | - 767 | 20394 | 2255 | 20171 |
| 2000 | 18,894,000 | 52915 | 23714 | 22886 | - 828 | 51907 | 2312 | 31587 |
| 2005 | 19,663,000 | 55242 | 24883 | 24009 | - 874 | 94929 | 2450 | 43528 |
| 2010 | 20,802,000 | 58568 | 26378 | 25442 | - 936 | 146352 | 2649 | 56362 |
| 2015 | 22,169,000 | 62544 | 28183 | 27176 | -1007 | 204269 | 2856 | 70237 |
| 2020 | 23,516,000 | 66497 | 30081 | 29007 | -1074 | 267782 | 3023 | 85041 |

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*Calculated from 1987

**Stage II greater than 5 cm or with positive nodes, Stage III, or Stage IV

***Detected while in early stages (stage 0, I, II <5 cm)

TABLE 9b

THE ANNUAL LOGISTIC AND FINANCIAL IMPACT
OF SCREENING 30% OF ASYMPTOMATIC WOMEN IN THE U.S.
AGE 65 THROUGH 74
WITH ANNUAL BREAST PHYSICAL EXAMINATIONS AND MAMMOGRAPHY
1987 TO 2020

USES BASELINE ASSUMPTIONS

| | No. Examinations and Workups (000s) | | Estimated Financial Costs to Medicare (000s $)* | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | No. Screens (9) | No. Workups (10) | Screens (11) | Workups (12) | Init'l Rx (13) | Cont'g Rx (14) | Term'l Rx Cancer (15) | Term'l Rx Other (16) | Annual Net Costs (17) | Cumulative Net Costs (18) |
| 1990 | 2773 | 55.5 | 138,645 | 49912 | - 1032 | 3478 | - 6154 | 250 | 185,098 | 737,110 |
| 1995 | 2791 | 55.8 | 139,556 | 50240 | - 1039 | 10150 | - 8267 | 1207 | 191,847 | 1,681,192 |
| 2000 | 2863 | 57.3 | 143,151 | 51535 | - 1066 | 16111 | - 8923 | 2585 | 203,393 | 2,672,826 |
| 2005 | 3037 | 60.7 | 151,853 | 54667 | - 1130 | 20557 | - 9423 | 3969 | 220,494 | 3,739,077 |
| 2010 | 3286 | 65.7 | 164,288 | 59144 | - 1222 | 23819 | -10083 | 5093 | 241,039 | 4,902,539 |
| 2015 | 3543 | 70.9 | 177,134 | 63768 | - 1318 | 26463 | -10857 | 5940 | 261,131 | 6,168,980 |
| 2020 | 3748 | 75 | 187,413 | 67469 | - 1395 | 28818 | -11577 | 6614 | 277,342 | 7,525,299 |

*1984 dollars, without discounting

TABLE 9c

THE ANNUAL LOGISTIC AND FINANCIAL IMPACT
OF SCREENING 30% OF ASYMPTOMATIC WOMEN IN THE U.S.
AGE 65 THROUGH 74
WITH ANNUAL BREAST PHYSICAL EXAMINATIONS AND MAMMOGRAPHY
1987 TO 2020

USES BASELINE ASSUMPTIONS

| | No. Examinations and Workups (000s) | | Estimated Financial Costs to Medicare (000s $)* | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | No. Screens (9) | No. Workups (10) | Screens (11) | Workups (12) | Init'l Rx (13) | Cont'g Rx (14) | Term'l Rx Cancer (15) | Term'l Rx Other (16) | Annual Net Costs (17) | Cumulative Net Costs (18) |
| 1990 | 2773 | 55.5 | 119,767 | 43116 | - 891 | 3004 | - 5316 | 216 | 159,895 | 686,017 |
| 1995 | 2791 | 55.8 | 94,457 | 34004 | - 703 | 6870 | - 5595 | 817 | 129,850 | 1,391,662 |
| 2000 | 2863 | 57.3 | 75,916 | 27330 | - 565 | 8544 | - 4732 | 1371 | 107,864 | 1,972,142 |
| 2005 | 3037 | 60.7 | 63,098 | 22715 | - 470 | 8542 | - 3915 | 1649 | 91,620 | 2,460,978 |
| 2010 | 3286 | 65.7 | 53,487 | 19256 | - 398 | 7755 | - 3283 | 1658 | 78,475 | 2,878,861 |
| 2015 | 3543 | 70.9 | 45,186 | 16267 | - 336 | 6751 | - 2770 | 1515 | 66,613 | 3,235,337 |
| 2020 | 3748 | 75 | 37,459 | 13485 | - 279 | 5760 | - 2314 | 1322 | 55,433 | 3,534,588 |

*1984 dollars, discounted at 5% from 1987

screening from ages 65 through 74, this probability decreases to about 23.3 percent, an absolute reduction in the chance of dying of 5.3 percent. For a woman destined to get breast cancer after age 65, 10 years of screening with mammography and breast physical examination will increase her expected lifetime about 258 days. For an asymptomatic woman, who might or might not even get breast cancer, 10 years of screening will increase her expected lifetime by approximately 13.4 days. The chance that a woman will develop a new breast cancer from the radiation associated with a single mammographic examination is less than one in 500,000. The chance that at any particular examination she will have a surgical recommendation for a lesion that is in fact not breast cancer is approximately two in 100, or 2 percent. Screening with mammography and breast physical examination not only reduces a woman's chance of dying of breast cancer but also changes the morbidity associated wich the disease; 10 years of screening will decrease the chance of getting a late stage breast cancer by approximately 10%.

Effect on the Medicare Population

The effect of screening a group of women depends not only on the age group that is offered screening but on the proportion of women in that group who are actually screened. Tables 9a, 9b and 9c show the effect on breast cancer cases, deaths and costs for all women in the United States over 65 (ages 65 to 100+) if 30 percent of women ages 65 through 74 are screened each year with annual breast physical examinations and mammography.

Column (1) of Table 9a gives the number of women in the United States who are 65 and older. The second column shows the number of breast cancer cases that can be expected among those women in each year. Column 3 gives the number of breast cancer deaths that can be expected in these women if there is no screening. The fourth column gives the number of deaths each year if 30 percent of the women are screened each year, under the baseline assumption of

the effectiveness of screening (see above). Column 5 shows the reduction in number of breast cancer deaths each year achieved by screening. Column 6 shows the cumulative number of person-years of life saved for women over age 65, from the beginning of the program in 1987 to various years in the future. (For example, screening 30% of women from age 65-74 in the U.S. starting in 1987 will save about 52,000 person-years of life by the year 2000.) Column 7 shows the annual number of late-stage breast cancers (stage II >5 cm or with positive nodes, stage III, and stage IV) prevented by screening 30% of women in the U.S. between ages 65 and 74.[18] Column 8 shows the cumulative number of late-stage breast cancers that would be prevented by screening, for various years in the future. The 10 columns in Tables 9b and 9c indicate the logistic and economic outcomes of screening. Table 9b shows costs to Medicare in 1984 dollars, undiscounted; Table 9c shows costs in 1984 dollars discounted 5%. Columns 9 and 10 show the number of women screened and number who receive workups for false-positive examinations if 30 percent of U.S. women in this age group are screened. Column 11 shows the total financial cost of providing screening to 30 percent of women in this age group, under the baseline assumption of a cost of $50 for an examination (i.e., $40 for a mammogram and $10 for a breast physical examination and office visit). Column 12 shows the additional expected cost of working up women who have false-positive screening examinations. Column 13 shows the savings in initial treatment costs caused by screening. Initial treatment costs will be reduced because more breast cancers will be found in earlier stages, when treatment is less expensive. The next column (14) indicates the increase in continuing care costs, because with screening, more women will be alive with the diagnosis of breast cancer, and will require continuing care. Column 15 shows the reduction in terminal care costs for breast cancer that would result from a reduction in breast cancer mortality. Column 16 shows the increase in terminal care costs for

other causes (because women who are prevented from dying of breast cancer will eventually die of other causes). Column 17 gives the net financial costs each year to the Medicare program resulting from this screening program. Finally, the last column (18) shows the cumulative net costs to Medicare for various years in the future (cumulative from 1987). Each row in the table indicates a particular year in the future. For example, in the year 2000, there will be approximately 18,894,000 women age 65 and older in the United States (column 1), and they will account for approximately 52,915 new cases of breast cancer (column 2). If these women are not screened, there will be approximately 23,714 deaths from breast cancer in this group (column 3). If 30 percent of women ages 65 through 74 are screened, this number will be reduced to 22,886 (column 4) -- a difference of 828 lives. From 1987 to 2000, approximately 51,907 person-years of life will be saved for women in the Medicare population (column 6). Of the breast cancer cases that occur in the absence of screening, in the year 2000, 2312 fewer will be detected in late stages (column 7) and by the year 2000 a total of 31,587 late-stage cancers will have been prevented (i.e., detected in early stages) (column 8). With regard to workups and costs (undiscounted), in the year 2000, screening 30 percent of asymptomatic women ages 65 through 74 will cause about 2,863,000 women (Table 9b, column 9) to be examined and about 57,300 (column 10) to have recommendations for surgical consultations for false-positive screening examinations. The screening examinations will cost approximately $143 million (column 11), and workups will cost approximately $51.5 million (column 12). Initial treatment costs will be reduced about $1.1 million (column 13) and terminal care costs for breast cancer will be reduced about $8.9 million (column 15). On the other hand, continuing care costs will be increased about $16.1 million (column 14), and the costs of terminal care for other causes of death will be increased about $2.6 million (column 16). The net costs to the

Medicare program in the year 2000 will be about $203 million (column 17). The cumulative costs to the Medicare program due to screening from 1987 to 2000 will be approximately $2.7 billion (column 18). Discounted costs are given in Table 9c.

Other age groups, costs, frequencies and risk groups. Tables 10 through 15 give the estimated effectiveness and costs of screening different age groups, cost assumptions, and frequencies. Tables 10 and 11 show the estimated effects of annual screening of women ages 65 through 84, and 65 and older, respectively, under the baseline assumptions of a $50 examination and 30 percent acceptance rate. Tables 12 through 14 show the estimated effects of annual screening of women ages 65 through 74, 65 through 84, and 65 and older, respectively, under the assumption of a $70 examination (and 30 percent acceptance rate). Table 15 gives the estimated effects of screening 30 percent of women ages 65 through 74 every two years, at a cost per examination of $50. For this calculation, it was assumed that biennial breast physical examination and mammography will be 75 percent as effective in reducing mortality as annual screening, reducing mortality 37.5 percent at five years, 30 percent at 10 years, and 22.5 percent at 20 years.[19] Tables 9-15 assume that screening is offered to all women, and that the average relative risk of the women who accept screening is 1. The effectiveness and efficiency of screening is increased if screening is focused on high-risk women, either by restricting coverage to specific high-risk groups (e.g., Carter, et al., 1987), or by only high-risk women electing to be screened. A method for estimating the impact of focusing on high-risk groups will be described in the section on "sensitivity analysis."

Discounting. Tables 9a and 9b give the estimated costs and effectiveness of screening without discounting. Table 9c gives the estimated costs of screening, discounted 5%. (Table 15c gives the estimated costs of

TABLE 10a

THE ANNUAL IMPACT ON MORTALITY AND MORBIDITY
OF SCREENING 30% OF ASYMPTOMATIC WOMEN IN THE U.S.
AGE 65 THROUGH 84
WITH ANNUAL BREAST PHYSICAL EXAMINATIONS AND MAMMOGRAPHY
1987 TO 2020

USES BASELINE ASSUMPTIONS

| Year | # Women 65-100 (1) | # Cases (2) | Breast Cancer Deaths | | |
|---|---|---|---|---|---|
| | | | No Screen (3) | Screen (4) | Diff. (5) |
| 1990 | 17,865,000 | 49461 | 21108 | 20161 | - 947 |
| 1995 | 18,405,000 | 51297 | 22602 | 21335 | -1267 |
| 2000 | 18,894,000 | 52915 | 23714 | 22352 | -1362 |
| 2005 | 19,663,000 | 55242 | 24883 | 23460 | -1424 |
| 2010 | 20,802,000 | 58568 | 26378 | 24872 | -1505 |
| 2015 | 22,169,000 | 62544 | 28183 | 26575 | -1609 |
| 2020 | 23,516,000 | 66497 | 30081 | 28362 | -1719 |

TABLE 10b

THE ANNUAL LOGISTIC AND FINANCIAL IMPACT
OF SCREENING 30% OF ASYMPTOMATIC WOMEN IN THE U.S.
AGE 65 THROUGH 84
WITH ANNUAL BREAST PHYSICAL EXAMINATIONS AND MAMMOGRAPHY
1987 TO 2020

USES BASELINE ASSUMPTIONS

| | No. Examinations and Workups (000s) | | Financial Costs (000s $)* | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | No. Screens (9) | No. Workups (10) | Screens (11) | Workups (12) | Init'l Rx (13) | Cont'g Rx (14) | Term'l Rx Cancer (15) | Term'l Rx Other (16) | Net Costs (17) |
| 1990 | 4509 | 90.2 | 225,463 | 81,167 | - 1743 | 5652 | - 10208 | 661 | 300,992 |
| 1995 | 4609 | 92.2 | 230,437 | 82,957 | - 1783 | 15795 | - 13655 | 2848 | 316,600 |
| 2000 | 4722 | 94.4 | 236,121 | 85,003 | - 1826 | 24105 | - 14680 | 5374 | 334,097 |
| 2005 | 4941 | 98.8 | 247,053 | 88,939 | - 1909 | 29817 | - 15344 | 7493 | 356,049 |
| 2010 | 5275 | 105.5 | 263,743 | 94,948 | - 2036 | 33778 | - 16218 | 9022 | 383,236 |
| 2015 | 5664 | 113.3 | 283,204 | 101,953 | - 2186 | 36982 | - 17341 | 10128 | 412,739 |
| 2020 | 6026 | 120.5 | 301,307 | 108,470 | - 2327 | 39975 | - 18519 | 11046 | 439,952 |

*1984 dollars, without discounting

TABLE 11a

THE ANNUAL IMPACT ON MORTALITY AND MORBIDITY
OF SCREENING 30% OF ALL ASYMPTOMATIC WOMEN IN THE U.S.
AGE 65 AND OLDER
WITH ANNUAL BREAST PHYSICAL EXAMINATIONS AND MAMMOGRAPHY
1987 TO 2020

USES BASELINE ASSUMPTIONS

| Year | # Women 65-100 (1) | # Cases (2) | Breast Cancer Deaths | | |
|---|---|---|---|---|---|
| | | | No Screen (3) | Screen (4) | Diff. (5) |
| 1990 | 17,865,000 | 49461 | 21108 | 20007 | -1101 |
| 1995 | 18,405,000 | 51297 | 22602 | 21136 | -1466 |
| 2000 | 18,894,000 | 52915 | 23714 | 22134 | -1579 |
| 2005 | 19,663,000 | 55242 | 24883 | 23232 | -1651 |
| 2010 | 20,802,000 | 58568 | 26378 | 24638 | -1740 |
| 2015 | 22,169,000 | 62544 | 28183 | 26332 | -1852 |
| 2020 | 23,516,000 | 66497 | 30081 | 28107 | -1974 |

TABLE 11b

THE ANNUAL LOGISTIC AND FINANCIAL IMPACT
OF SCREENING 30% OF ALL ASYMPTOMATIC WOMEN IN THE U.S.
AGE 65 AND OLDER
WITH ANNUAL BREAST PHYSICAL EXAMINATIONS AND MAMMOGRAPHY
1987 TO 2020

USES BASELINE ASSUMPTIONS

| | No. Examinations and Workups (000s) | | Financial Costs (000s $)* | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | No. Screens (9) | No. Workups (10) | Screens (11) | Workups (12) | Init'l Rx (13) | Cont'g Rx (14) | Term'l Rx Cancer (15) | Term'l Rx Other (16) | Net Costs (17) |
| 1990 | 5228 | 104.6 | 261,385 | 94,099 | - 2063 | 6430 | - 11863 | 1061 | 349,048 |
| 1995 | 5409 | 108.2 | 270,445 | 97,360 | - 2140 | 17414 | - 15798 | 3919 | 371,199 |
| 2000 | 5577 | 111.5 | 278,826 | 100,377 | - 2207 | 26145 | - 17020 | 6815 | 392,937 |
| 2005 | 5828 | 116.6 | 291,394 | 104,902 | - 2304 | 32063 | - 17796 | 9119 | 417,378 |
| 2010 | 6188 | 123.8 | 309,390 | 111,380 | - 2443 | 36135 | - 18746 | 10744 | 446,461 |
| 2015 | 6613 | 132.3 | 330,645 | 119,032 | - 2609 | 39426 | - 19959 | 11916 | 478,451 |
| 2020 | 7029 | 140.6 | 351,432 | 126,516 | - 2774 | 42525 | - 21271 | 12907 | 509,336 |

*1984 dollars, without discounting

TABLE 12a

THE ANNUAL IMPACT ON MORTALITY AND MORBIDITY
OF SCREENING 30% OF ASYMPTOMATIC WOMEN IN THE U.S.
AGE 65 THROUGH 74
WITH ANNUAL BREAST PHYSICAL EXAMINATIONS AND MAMMOGRAPHY
1987 TO 2020

ASSUMES $70 EXAMINATION

| Year | # Women 65-100 (1) | # Cases (2) | Breast Cancer Deaths | | |
|---|---|---|---|---|---|
| | | | No Screen (3) | Screen (4) | Diff. (5) |
| 1990 | 17,865,000 | 49461 | 21108 | 20537 | - 571 |
| 1995 | 18,405,000 | 51297 | 22602 | 21835 | - 767 |
| 2000 | 18,894,000 | 52915 | 23714 | 22886 | - 828 |
| 2005 | 19,663,000 | 55242 | 24883 | 24009 | - 874 |
| 2010 | 20,802,000 | 58568 | 26378 | 25442 | - 936 |
| 2015 | 22,169,000 | 62544 | 28183 | 27176 | -1007 |
| 2020 | 23,516,000 | 66497 | 30081 | 29007 | -1074 |

TABLE 12b

THE ANNUAL LOGISTIC AND FINANCIAL IMPACT
OF SCREENING 30% OF ASYMPTOMATIC WOMEN IN THE U.S.
AGE 65 THROUGH 74
WITH ANNUAL BREAST PHYSICAL EXAMINATIONS AND MAMMOGRAPHY
1987 TO 2020

ASSUMES $70 EXAMINATION

| | No. Examinations and Workups (000s) | | Financial Costs (000s $)* | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | No. Screens (9) | No. Workups (10) | Screens (11) | Workups (12) | Init'l Rx (13) | Cont'g Rx (14) | Term'l Rx Cancer (15) | Term'l Rx Other (16) | Net Costs (17) |
| 1990 | 2773 | 55.5 | 194,103 | 49912 | - 1032 | 3478 | - 6154 | 250 | 240,556 |
| 1995 | 2791 | 55.8 | 195,379 | 50240 | - 1039 | 10150 | - 8267 | 1207 | 247,670 |
| 2000 | 2863 | 57.3 | 200,412 | 51535 | - 1066 | 16111 | - 8923 | 2585 | 260,654 |
| 2005 | 3037 | 60.7 | 212,595 | 54667 | - 1130 | 20557 | - 9423 | 3969 | 281,235 |
| 2010 | 3286 | 65.7 | 230,003 | 59144 | - 1222 | 23819 | -10083 | 5093 | 306,754 |
| 2015 | 3543 | 70.9 | 247,988 | 63768 | - 1318 | 26463 | -10857 | 5940 | 331,985 |
| 2020 | 3748 | 75 | 262,378 | 67469 | - 1395 | 28818 | -11577 | 6614 | 352,307 |

*1984 dollars, without discounting

TABLE 13a

THE ANNUAL IMPACT ON MORTALITY AND MORBIDITY
OF SCREENING 30% OF ASYMPTOMATIC WOMEN IN THE U.S.
AGE 65 THROUGH 84
WITH ANNUAL BREAST PHYSICAL EXAMINATIONS AND MAMMOGRAPHY
1987 TO 2020

ASSUMES $70 EXAMINATION

| Year | # Women 65-100 (1) | # Cases (2) | Breast Cancer Deaths | | |
|---|---|---|---|---|---|
| | | | No Screen (3) | Screen (4) | Diff. (5) |
| 1990 | 17,865,000 | 49461 | 21108 | 20161 | - 947 |
| 1995 | 18,405,000 | 51297 | 22602 | 21335 | -1267 |
| 2000 | 18,894,000 | 52915 | 23714 | 22352 | -1362 |
| 2005 | 19,663,000 | 55242 | 24883 | 23460 | -1424 |
| 2010 | 20,802,000 | 58568 | 26378 | 24872 | -1505 |
| 2015 | 22,169,000 | 62544 | 28183 | 26575 | -1609 |
| 2020 | 23,516,000 | 66497 | 30081 | 28362 | -1719 |

TABLE 13b

THE ANNUAL LOGISTIC AND FINANCIAL IMPACT
OF SCREENING 30% OF ASYMPTOMATIC WOMEN IN THE U.S.
AGE 65 THROUGH 84
WITH ANNUAL BREAST PHYSICAL EXAMINATIONS AND MAMMOGRAPHY
1987 TO 2020

ASSUMES $70 EXAMINATION

| | No. Examinations and Workups (000s) | | Financial Costs (000s $)* | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | No. Screens (9) | No. Workups (10) | Screens (11) | Workups (12) | Init'l Rx (13) | Cont'g Rx (14) | Term'l Rx Cancer (15) | Term'l Rx Other (16) | Net Costs (17) |
| 1990 | 4509 | 90.2 | 315,648 | 81,167 | - 1743 | 5652 | - 10208 | 661 | 391,177 |
| 1995 | 4609 | 92.2 | 322,612 | 82,957 | - 1783 | 15795 | - 13655 | 2848 | 408,775 |
| 2000 | 4722 | 94.4 | 330,569 | 85,003 | - 1826 | 24105 | - 14680 | 5374 | 428,545 |
| 2005 | 4941 | 98.8 | 345,874 | 88,939 | - 1909 | 29817 | - 15344 | 7493 | 454,871 |
| 2010 | 5275 | 105.5 | 369,240 | 94,948 | - 2036 | 33778 | - 16218 | 9022 | 488,734 |
| 2015 | 5664 | 113.3 | 396,485 | 101,953 | - 2186 | 36982 | - 17341 | 10128 | 526,020 |
| 2020 | 6026 | 120.5 | 421,830 | 108,470 | - 2327 | 39975 | - 18519 | 11046 | 560,475 |

*1984 dollars, without discounting

TABLE 14a

THE ANNUAL IMPACT ON MORTALITY AND MORBIDITY
OF SCREENING 30% OF ALL ASYMPTOMATIC WOMEN IN THE U.S.
AGE 65 AND OLDER
WITH ANNUAL BREAST PHYSICAL EXAMINATIONS AND MAMMOGRAPHY
1987 TO 2020

ASSUMES $70 EXAMINATION

| Year | # Women 65-100 (1) | # Cases (2) | Breast Cancer Deaths | | |
|---|---|---|---|---|---|
| | | | No Screen (3) | Screen (4) | Diff. (5) |
| 1990 | 17,865,000 | 49461 | 21108 | 20007 | -1101 |
| 1995 | 18,405,000 | 51297 | 22602 | 21136 | -1466 |
| 2000 | 18,894,000 | 52915 | 23714 | 22134 | -1579 |
| 2005 | 19,663,000 | 55242 | 24883 | 23232 | -1651 |
| 2010 | 20,802,000 | 58568 | 26378 | 24638 | -1740 |
| 2015 | 22,169,000 | 62544 | 28183 | 26332 | -1852 |
| 2020 | 23,516,000 | 66497 | 30081 | 28107 | -1974 |

TABLE 14b

THE ANNUAL LOGISTIC AND FINANCIAL IMPACT
OF SCREENING 30% OF ALL ASYMPTOMATIC WOMEN IN THE U.S.
AGE 65 AND OLDER
WITH ANNUAL BREAST PHYSICAL EXAMINATIONS AND MAMMOGRAPHY
1987 TO 2020

ASSUMES $70 EXAMINATION

| | No. Examinations and Workups (000s) | | Financial Costs (000s $)* | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | No. Screens (9) | No. Workups (10) | Screens (11) | Workups (12) | Init'l Rx (13) | Cont'g Rx (14) | Term'l Rx Cancer (15) | Term'l Rx Other (16) | Net Costs (17) |
| 1990 | 5228 | 104.6 | 365,939 | 94,099 | - 2063 | 6430 | - 11863 | 1061 | 453,602 |
| 1995 | 5409 | 108.2 | 378,622 | 97,360 | - 2140 | 17414 | - 15798 | 3919 | 479,377 |
| 2000 | 5577 | 111.5 | 390,357 | 100,377 | - 2207 | 26145 | - 17020 | 6815 | 504,467 |
| 2005 | 5828 | 116.6 | 407,951 | 104,902 | - 2304 | 32063 | - 17796 | 9119 | 533,936 |
| 2010 | 6188 | 123.8 | 433,146 | 111,380 | - 2443 | 36135 | - 18746 | 10744 | 570,217 |
| 2015 | 6613 | 132.3 | 462,903 | 119,032 | - 2609 | 39426 | - 19959 | 11916 | 610,709 |
| 2020 | 7029 | 140.6 | 492,005 | 126,516 | - 2774 | 42525 | - 21271 | 12907 | 649,909 |

*1984 dollars, without discounting

TABLE 15a

THE ANNUAL IMPACT ON MORTALITY AND MORBIDITY
OF SCREENING 30% OF ASYMPTOMATIC WOMEN IN THE U.S.
AGE 65 THROUGH 74
WITH BIENNIAL BREAST PHYSICAL EXAMINATIONS AND MAMMOGRAPHY
1987 TO 2020

| Year | # Women 65-100 in the US (1) | # Cases (2) | Impact on Breast Cancer Deaths: Annual Impact: No Screening (3) | With Screen (4) | Diff. (5) | Cumulative* # of Person-Years of Life Saved (6) | Impact on Breast Cancer Morbidity: Annual # of Late Stage** Cases Prevented*** (7) | Cumulative* # of Late Stage** Cases Prevented*** (8) |
|---|---|---|---|---|---|---|---|---|
| 1990 | 17,865,000 | 49461 | 21108 | 20668 | - 440 | 2705 | 1681 | 6694 |
| 1995 | 18,405,000 | 51297 | 22602 | 22040 | - 562 | 15674 | 1691 | 15128 |
| 2000 | 18,894,000 | 52915 | 23714 | 23113 | - 601 | 39213 | 1734 | 23690 |
| 2005 | 19,663,000 | 55242 | 24883 | 24245 | - 639 | 71053 | 1838 | 32646 |
| 2010 | 20,802,000 | 58568 | 26378 | 25688 | - 689 | 109063 | 1987 | 42272 |
| 2015 | 22,169,000 | 62544 | 28183 | 27439 | - 745 | 151939 | 2142 | 52678 |
| 2020 | 23,516,000 | 66497 | 30081 | 29286 | - 795 | 199031 | 2267 | 63781 |

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*Calculated from 1987

**Stage II greater than 5 cm or with positive nodes, Stage III, or Stage IV

***Detected while in early stages (stage 0, I, II <5 cm)

TABLE 15b

THE ANNUAL LOGISTIC AND FINANCIAL IMPACT
OF SCREENING 30% OF ASYMPTOMATIC WOMEN IN THE U.S.
AGE 65 THROUGH 74
WITH BIENNIAL BREAST PHYSICAL EXAMINATIONS AND MAMMOGRAPHY
1987 TO 2020

| | No. Examinations and Workups (000s) | | Estimated Financial Costs to Medicare (000s $)* | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | No. Screens (9) | No. Workups (10) | Screens (11) | Workups (12) | Init'l Rx (13) | Cont'g Rx (14) | Term'l Rx Cancer (15) | Term'l Rx Other (16) | Annual Net Costs (17) | Cumulative Net Costs (18) |
| 1990 | 1386 | 27.7 | 69,323 | 24956 | - 693 | 2728 | - 4739 | 196 | 91,770 | 365,132 |
| 1995 | 1396 | 27.9 | 69,778 | 25120 | - 698 | 7676 | - 6061 | 908 | 96,723 | 837,800 |
| 2000 | 1432 | 28.6 | 71,576 | 25767 | - 715 | 11971 | - 6476 | 1901 | 104,024 | 1,342,351 |
| 2005 | 1519 | 30.4 | 75,926 | 27334 | - 759 | 15194 | - 6887 | 2900 | 113,708 | 1,890,663 |
| 2010 | 1643 | 32.9 | 82,144 | 29572 | - 820 | 17613 | - 7428 | 3728 | 124,808 | 2,492,279 |
| 2015 | 1771 | 35.4 | 88,567 | 31884 | - 885 | 19605 | - 8028 | 4367 | 135,510 | 3,148,957 |
| 2020 | 1874 | 37.5 | 93,707 | 33734 | - 936 | 21377 | - 8567 | 4879 | 144,193 | 3,853,591 |

*1984 dollars, without discounting

TABLE 15c

THE ANNUAL LOGISTIC AND FINANCIAL IMPACT
OF SCREENING 30% OF ASYMPTOMATIC WOMEN IN THE U.S.
AGE 65 THROUGH 74
WITH BIENNIAL BREAST PHYSICAL EXAMINATIONS AND MAMMOGRAPHY
1987 TO 2020

| | No. Examinations and Workups (000s) | | Estimated Financial Costs to Medicare (000s $)* | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | No. Screens (9) | No. Workups (10) | Screens (11) | Workups (12) | Init'l Rx (13) | Cont'g Rx (14) | Term'l Rx Cancer (15) | Term'l Rx Other (16) | Annual Net Costs (17) | Cumulative Net Costs (18) |
| 1990 | 1386 | 27.7 | 59,884 | 21558 | - 599 | 2357 | - 4094 | 169 | 79,274 | 339,825 |
| 1995 | 1396 | 27.9 | 47,228 | 17002 | - 472 | 5195 | - 4102 | 615 | 65,466 | 692,995 |
| 2000 | 1432 | 28.6 | 37,958 | 13665 | - 379 | 6348 | - 3434 | 1008 | 55,166 | 988,268 |
| 2005 | 1519 | 30.4 | 31,549 | 11358 | - 315 | 6313 | - 2862 | 1205 | 47,248 | 1,239,611 |
| 2010 | 1643 | 32.9 | 26,744 | 9628 | - 267 | 5734 | - 2418 | 1214 | 40,634 | 1,455,679 |
| 2015 | 1771 | 35.4 | 22,593 | 8133 | - 226 | 5001 | - 2048 | 1114 | 34,568 | 1,640,512 |
| 2020 | 1874 | 37.5 | 18,729 | 6743 | - 187 | 4273 | - 1712 | 975 | 28,820 | 1,795,973 |

*1984 dollars, discounted at 5% from 1987

screening, discounted 5%, for a biennial screening program.) The effect of discounting the benefits of screening in future years (columns 5 and 7 of Table 9a), and the effects of different discount rates for costs can be calculated as follows. The effect of any discount rate (r) on the estimates for any year (Y) can be calculated by multiplying the estimate of interest (E) by a factor (F), which is calculated as follows: $F = E(1/1+r)Y-1987$. For example, in the base case (Table 9b) without discounting the net cost in the year 2000 is estimated to be $203,393,000 (column 17). If a discount rate of 5 percent is assumed, the discounted estimate becomes $107,864,000 (203,393,000 x (1/1.05)2000-1987 = 107,864,000) (column 17 of Table 9c).

Limitations

The estimated effects of screening shown in Tables 8 through 15 depend on the assumptions used in executing the model. Many of the assumptions are based on data from standard sources. Examples are the age- and sex-distributions of the U.S. population in 1980 (Census Bureau); and the age- and sex-specific mortality rates due to various cancers, to cardiovascular disease, and to other causes of death (Vital Statistics). Other assumptions pertain to the effectiveness and costs of screening and are particular to this analysis. Although these assumptions are based on the best available evidence, nevertheless, there is uncertainty about them, and different assumptions can alter the estimated costs and effectiveness of the screening programs being analyzed.

Effectiveness of screening in reducing mortality. Because there are no controlled studies that specifically report the reduction in mortality achieved by screening with current mammography techniques in women over age 65 in the United States, either annually or biennially, there is considerable uncertainty about the assumed reductions in mortality. There is also uncertainty about the effectiveness of biennial screening. A method for

estimating the impact of different assumptions will be described.

Stage proportions. There is little information from controlled trials on how annual screening of women 65 and older will change the proportions of breast cancers found in various stages. The proportions used to estimate the effect of screening on mortality were defined to achieve the assumed reduction in mortality. It is possible that other stage proportions would achieve the same reduction in mortality. Uncertainty about these stage proportions will affect the estimated savings in initial treatment costs caused by screening. The implications will be described below. To estimate the reduction in number of late-stage breast cancers (i.e., detecting these cases while still in early stages), the stage proportions observed in the BCDDP for women over age 50 were compared with stage proportions in SEER. If women who elected to be screened in the BCDDP were more likely than average to seek care for cancers in early stages in the absence of screening (i.e., more health conscious), this could cause the number of late-stage cancers prevented to be overestimated.

Financial costs. Costs to Medicare for initial treatment, continuing care, and terminal care were derived from Medicare data that include only hospitalized patients. Because some breast cancer patients are never hospitalized, and because nonhospitalized patients can be expected to have lower costs than hospitalized patients, these data might overestimate actual charges. However, because the proportion of breast cancer patients who are never hospitalized is very small, the error is expected to be negligible. The implications will be discussed.

Calculation method. The model calculates the effects of screening based on the shift in stage and reduction in mortality that result during each year screening is offered. A simplifying assumption is that the stage proportions and reduction in mortality for screened people are constant for each year of

screening, and revert to the stage proportions for unscreened women when screening ends. In fact, the changes in stage proportions and reduction in mortality achieved by screening are not constant for all years during screening, and can persist a few years after screening ends. For example, stage proportions and reduction in mortality are typically different in the first year of screening (when "prevalence cases" are detected) than in subsequent years of screening (when "incidence cases" are detected). Furthermore, some effect on stage proportions and mortality can be observed for a few years after screening is terminated. Both of these are controlled by the lead time of screening. In the case of screening for breast cancer, the lead time in this age group ranges from 1 to 5 years, indicating that any errors introduced by this simplifying assumption should be small.

Proportion of women who accept screening. The results are based on the baseline assumption that 30 percent of women who are offered screening will accept it. There is virtually no evidence for estimating this parameter. Furthermore, it is quite likely that the proportion of women who accept screening will be different for different age groups (e.g., higher for women ages 65 to 70 than for women 90 to 95). While the model can calculate the implications of any set of assumptions, including variances in age and acceptance rates, there is no basis for determining a preferable estimate. A method for calculating the impact of different assumptions will be described.

Sensitivity Analysis

The impact of different assumptions about many of the most important parameters can easily be explored. The relative importance of changing different assumptions is indicated by examining the impact of changing each assumption by the same proportion (say, 10 percent) (see Table 16). The most important assumption, directly controlling both the reduction in breast cancer deaths and net costs, is the proportion of women who accept screening. A 10

TABLE 16

EFFECT ON BASELINE ESTIMATE* OF NUMBER OF BREAST CANCER DEATHS AND NET COSTS IN THE YEAR 2000 CAUSED BY CHANGING REFERENCE ASSUMPTIONS BY 10%

| FACTOR | REFERENCE ASSUMPTION | EFFECT OF CHANGING REFERENCE ASSUMPTION BY 10 PERCENT | |
|---|---|---|---|
| | | CHANGE IN BREAST CANCER DEATHS | CHANGE IN NET COSTS |
| proportion of women who accept screening | 30% | 10% | 10% |
| relative risk of women who accept screening | 1 | 10% | 0.43% |
| reduction in mortality caused by screening | 50% at 5 years<br>30% at 20 years | 10% | 0.43% |
| false-positive rate of screening | 2% | 0% | 2.53% |
| cost to Medicare | | | |
| - screening mammography and breast physical examination | $ 50 | 0% | 7.04% |
| - workup | $ 900 | 0% | 2.53% |
| - initial treatment (avg. cost for all stages) | $ 5291 | 0% | 0.05% |
| - continuing care | $ 183 | 0% | 0.79% |
| - terminal care (breast cancer) | $10776 | 0% | 0.44% |
| - terminal care (other causes) | $ 7618 | 0% | 0.13% |

*The base case uses the assumptions listed in Table 3 and estimates the effects of screening 30% of average-risk women age 65-74, starting in 1987. The base case estimates are given in Tables 5a and 5b.

percent change in this variable causes a 10 percent change in both breast cancer deaths and net costs. The relative risk of women who accept screening, and the reduction in mortality caused by screening, also affect the extent to which screening reduces the number of women dying of breast cancer in the year 2000. However, their impact on net costs is much smaller. Changing the assumed false-positive rate by 10 percent (e.g., reducing it from 2 percent to 1.8 percent), and changing the assumed cost of a workup by 10 percent (e.g., from $900 to $990), have moderate effects on the net costs associated with screening, changing the estimate by about 2.5 percent. For any proportion of women screened, by far the biggest determinant of net costs is the assumed cost of the screening examinations; a 10 percent change in this variable (e.g., from $50 to $55) will increase net costs by about 7 percent. Put another way, a $5 increase in the cost of screening examinations will increase the net costs of screening in the year 2000 by more than $14 million (7.04% x $203,393,000 = $14,318,867). Uncertainty about the cost of treatment is relatively unimportant. A 10 percent change in any of the treatment-cost parameters (excluding workups) will change the estimated net costs by less than 1 percent. Of all the cost factors, uncertainty about the cost of continuing care has the greatest effect, and uncertainty about the cost of initial treatment has the least effect on net costs. Assumptions about the false-positive rate and costs of screening and treatment do not affect the number of breast cancer deaths.

To estimate the effect of specific changes in assumptions, multiply the appropriate columns in the tables by a factor that is calculated as the new assumption divided by the old assumption.

Effectiveness of screening. The reference assumption is that annual breast physical examination and mammography will reduce breast cancer mortality by 50 percent at five years and 30 percent at 20 years. If the

actual effect is half as great (i.e., 25 percent at five years and 15 percent at 20 years), then the answers to questions 5 to 8 and 13 of Table 12 are multiplied by 0.5 (25/50 = 0.5). Similarly, for Table 9a, the revised effectiveness is found by multiplying the figures in column 5 by 0.5 and recalculating column 4 as [column 3 - the new column 5]. The revised costs in Tables 9b and 9c are found by multiplying the entries in columns 13 to 16 by 0.5 and recalculating column 17 as the sum of columns 11 to 16. If the effectiveness of screening is 3/2 as great as the baseline assumption (i.e., 75 percent at five years and 45 percent at 20 years), the answers to questions 5 to 8 and 13 in Table 12 are multiplied by 1.5 (75/50 = 1.5), and column 5 of Table 9a is multiplied by 1.5. Analogous modifications can be made to columns 13 through 16 of Tables 9b and 9c, and column 17 should be recalculated as the sum of columns 11 through 16. If the new assumptions for the reduction in mortality at five and 20 years are not the same multiples of 50 percent and 30 percent, respectively, the calculations are more complicated, but an approximate estimate can be obtained by averaging the two multiples. For example, if the new assumption is a mortality reduction of 40 percent at five years and 20 percent at 20 years, the multipliers are 0.8 (40/50 = 0.8) and 0.67 (20/30 = 0.67), and an approximate factor of 0.735 can be used (the average of 0.8 and 0.67).

Stage proportions. Uncertainty about stage proportions affects the number of late stage cancers prevented by screening, as well as the potential reduction in initial treatment costs caused by screening. The reduction in late-stage cancers was based on a comparison of the stage proportions in the BCDDP for all women over age 50 versus the stage proportions in SEER for women over age 50 (Seidman et al., 1987). Because the effectiveness of screening in women age 50 to 65 might well overestimate the effectiveness in the over-65 age group, the estimates in columns 7 and 8 in Tables 9 and 15 might

overestimate the true impact of screening on late-stage cancers. With respect to the potential savings in initial care costs, use of different assumptions about the shift in stage can modify the results reported in the tables, but any modifications across a reasonable range will have a very small effect on the net costs associated with screening. The absolute maximum amount of savings that could be achieved (assuming that screening detects every case in stage 0) would, in the year 2000, be approximately $500 per cancer patient screened, which represents an overall savings of approximately $8 million or less than 4 percent of the net costs. Thus the maximum error that uncertainty about these parameters could introduce is to modify the net costs by 4 percent.

Radiation. Because the carcinogenic effect of radiation is negligible, altering the estimated radiation hazard within a reasonable range will have virtually no effect on any outcomes listed in the tables.

False-positive rate. The reference assumption is that at any screening examination, 2 percent of women over 50 will have false-positive results leading to a recommendation for biopsy. If this false-positive rate is, say, 1 percent instead of 2 percent, the entries in columns 10 and 12 of Tables 9b and 9c are multiplied by 0.5 (1/2 = 0.5). Column 17 of Tables 9b and 9c must then be recalculated as the sum of columns 11 to 16.

Costs of screening mammography and breast physical examination. The costs of screening mammography and breast physical examination have a large effect on net costs. The reference assumption is that screening mammography and breast physical examination will cost Medicare $50. Altering this amount will modify column 11 of Tables 9b and 9c. If the cost of the examination is, say, $100, then the entries in column 11 must be multiplied by 2 (100/50 = 2). Column 17 must then be recalculated as the sum of columns 11 to 16. The original cost of $50 was based on an assumed cost of $40 for screening

mammography and $10 for screening breast physical examination. There is considerable uncertainty about the cost to Medicare of a screening breast physical examination, which might require a physician visit, and the cost of this examination might be as high as $30. This would increase the total cost of the two examinations to $70. Given the importance of this parameter, the effects have been recalculated (shown in Tables 12-14) assuming a $70 cost for the two procedures.

Cost of workup. The reference assumption is that a workup will cost Medicare an average of $900. Altering this amount will affect column 12 of Tables 9b and 9c (and column 17 must be recalculated as the sum of columns 11 to 16).

Cost of initial treatment. Different assumptions about the cost of initial treatment are difficult to calculate precisely. However, the magnitude of savings in initial treatment costs is very small relative to the net costs associated with screening (the savings are only 1/2 of 1 percent of the net costs), and modifying the assumed initial treatment costs within a reasonable range will have little effect on net costs.

Continuing care. The continuing care costs, calculated from Medicare data, are approximately $183 per month or $2196 per year. A different assumption will modify column 14 of Tables 9b and 9c. For example, if continuing care costs are assumed to be $1000 per year instead of $2196, the entries in column 14 should be multiplied by 0.455 (1000/2196 = 0.455). Column 17 must then be recalculated as the sum of columns 11 to 16.

Terminal care. Modifying the assumed cost to Medicare of terminal care for breast cancer or other causes would alter columns 15 or 16 of Tables 9b and 9c, respectively. The calculations would be performed as described for other parameters. If either column 15 or 16 is changed, column 17 must be recalculated as the sum of columns 11 to 16.

Proportion of women who accept screening. The reference assumption was that 30 percent of women would accept screening. This parameter affects columns 5, and 9 through 17 of Tables 9a, 9b and 9c. Specifically, if the proportion accepting screening is, say, 20 percent, then the entries in each of these columns should be multiplied by 0.67 (20/30 = 0.667).

Relative risk of screened women. The reference assumption is that the screened women are average risk, that is, the relative risks of all the women in the screened group must average out to 1. If the risk of the screened women is different, this will affect column 5 of Table 9a. Specifically, if the women who accept screening tend to be at high risk, with a relative risk for the group of, say, 2, then the entries in column 5 should be multiplied by 2 (2/1 = 2). Column 4 must then be recalculated as [column 3 - the new column 5]. Changing the relative risk of the screened group will also change columns 13 to 16 in an analogous fashion (column 17 must then be recalculated as the sum of columns 11 to 16).

Age group screened. Tables 8, 9 and 12 estimate the effect of offering screening to women ages 65 through 74. Other policies are possible, such as offering screening to women age 65 through 84, or to all women over age 65 (65 to 100+). There is no simple way to modify Tables 8, 9 or 12 to estimate the effects of changing the age groups offered screening. To indicate the effects of screening different age groups, Tables 10, 11, 13 and 14 show the results of offering annual screening to women ages 65 through 84 (Tables 10 and 13), and to all women ages 65 and older (Tables 11 and 14). All these tables assume a 30 percent acceptance rate. Tables 10 and 11 assume a $50 cost per examination and Tables 13 and 14 assume a $70 cost per examination.

Frequency. The relative value of screening at different frequencies is determined by the natural history of breast cancer--how long it takes a cancer to progress from being first detectable by mammography to developing obvious

signs and symptoms. The longer this "preclinical interval," the greater the proportion of effectiveness retained as the screening interval is lengthened. Calculating the actual impact of screening at various frequencies is very complicated, but some general rules apply. A lower bound is that whatever the natural history, doubling the time between screenings will--in the worst case--cut the effectiveness in half (i.e., screening will be about 50 percent as effective as if done annually), tripling the interval will do no worse than to cut the effectiveness to a third, and so forth. In the case of breast cancer in women over age 65, the preclinical interval appears to be more than 2 to 3 years, so the degree of effectiveness retained will be considerably better than the worst case. This is reinforced by the Swedish study in which screening every 20 to 36 months still delivered a 15-40 percent decrease in mortality.

Given that different frequencies affect both effectiveness and cost, we assumed that biennial examinations will deliver 75 percent of the effectiveness of annual examinations. The results of screening 30 percent of women ages 65 through 74 are shown in Table 15, under the assumption that biennial screening will reduce mortality in screened women by approximately 37.5 percent at five years, 30 percent at 10 years, and 22.5 percent at 20 years. Of course, biennial screening will reduce the cost of screening, the number of false-positive results, and the cost of workups each year by a factor of two.

Summary of Analysis of Effectiveness and Costs

The following conclusions and estimates appear justified by the existing evidence.

- A woman who reaches age 65 still has about a five percent chance of developing breast cancer and about a one-and-one-half percent chance of dying of it.

- There is good evidence that annual screening for breast cancer with mammography and breast physical examination will reduce this morbidity and mortality. A reasonable estimate is that for a woman destined to get breast cancer, annual screening with these two modalities will increase the chance she survives 10 years by about 40%.

- The radiation hazard in this age group is virtually nil.

- False-positive examinations, which can lead to biopsies, occur in about two percent of women screened.

- The cost of mammography varies widely, ranging from $25 to more than $200. However, many centers have shown that high quality screening mammography can be offered at a reasonable profit for $40, and the combination of mammography and breast physical examination can be obtained for $50.

- From the viewpoint of an individual average-risk 65-year-old woman, the effects of being screened will depend on the ages of screening, and the protocol (e.g., annual versus biennial examinations). A sense of the magnitude of the effects is provided by examining a program of annual screening from age 65-74 (assuming perfect compliance). Such a program will decrease the chance a 65-year-old woman will die of breast cancer from 149 per 10,000 to 121 per 10,000 -- an absolute reduction of 28 per 10,000, a relative reduction of 19%. The chance 10 years of annual mammograms will cause a new case

of breast cancer, due to the potential carcinogenic effect of x-rays, is less than one per 500,000. The chance of not detecting a breast cancer until after it has reached a late stage (stage 2 >5 cm or with positive nodes, stage III or stage IV) is decreased from 305 per 10,000 to about 224 per 10,000 -- an absolute decrease of about 81 per 10,000, a relative decrease of about 10%. If costs and life years are not discounted, the cost of adding a year of life expectancy is approximately $18,900. If costs are discounted 5% (but life-years are not discounted) the cost per year of life gained is approximately $14,500. If both life-years and costs are discounted at 5%, the cost per year of life gained is approximately $27,500.

o For the Medicare program, the health and economic impacts of covering breast cancer screening will depend on the specific age groups covered, the particular screening protocol offered, and the proportion of women who actually accept an offer to be screened. Furthermore, the impact of screening on breast cancer mortality and costs will change each year as the long-term impact of earlier diagnosis and treatment takes effect. A sense of the magnitude of the potential benefits and costs is gained by considering a program consisting of annual breast physical examinations and mammograms offered to women age 65 to 74, with 30% of women accepting. Starting such a program in 1987 would decrease the number of women who will die of breast cancer in the year 2000 by approximately 830, increasing to approximately 1075 in the year 2020. For a program begun in 1987, a total of approximately 52,000 person-years of life would have been saved and a total of approximately 31,500 late-stage breast cancers prevented (by detecting them while still in early

stages) by the year 2000. By the year 2020, such a program would have saved a total of approximately 268,000 person-years of life and prevented a total of approximately 85,000 late-stage breast cancers.

o Breast cancer screening can not be expected to save enough money in decreased treatment costs to offset the costs to Medicare of screening and workups. For example, screening 30% of women age 65-75 will involve screening approximately three million women each year and working up approximately 60,000 women each year for false-positive test results. In 1984 dollars the net costs to the Medicare program (taking into account screening, workups, initial treatment, continuing care and terminal care) will range from approximately $185 million (in the year 1990) to approximately $277 million (in the year 2020). By the year 2000 the cumulative costs to Medicare will be approximately $2.7 billion, increasing to approximately $7.5 billion by the year 2020. By the year 2020 this amounts to a cost of approximately $28,000 per year of life saved for women over age 65 covered by the Medicare Program.

o If costs are discounted at 5%, the annual costs to the Medicare program become approximately $108 million in the year 2000, decreasing to approximately $55 million in the year 2020. The cumulative costs (discounted 5%) are approximately $2 billion by 2000 and $3.5 billion by 2020. If costs are discounted 5% (but life-years are not discounted), by the year 2020 the cost to the Medicare program for each person-year of life saved is approximately $13,200. If both costs and life-years are discounted 5%, by the year 2020 the cost to the Medicare program for each person-year of life saved is

approximately $34,600.

- A screening protocol consisting of biennial mammograms and breast physical examinations (every two years) would retain approximately 75% of the benefits at approximately half the cost, compared with annual screening. For example, a program to screen 30% of women between age 65-75 with biennial mammograms and breast physical examinations would involve screening only about 1.5 million women each year with mammography and breast physical examination, and working up only about 30,000 women for false-positive examinations. The annual net costs to the Medicare program (undiscounted) would be on the order of $100 million each year (approximately $104 million in 2000, and $144 million in 2020). The cumulative costs to Medicare (undiscounted) would be approximately $1.3 billion by the year 2000 and $3.8 billion by 2020.

## PART IV: RESOURCES FOR BREAST CANCER SCREENING

This staff paper analyzes the cost-effectiveness of large-scale mammographic screening of asymptomatic women in the Medicare population. The numbers of women who would be affected by such a screening program in future years, the associated costs, and the expected life-years saved by early detection and treatment of breast cancer are issues discussed elsewhere in this staff paper. This section deals with the current and future availability of health care resources for large-scale mammographic screening.

### Current Delivery and Use of Screening Mammography Services

#### How Breast Cancer is Diagnosed

As discussed earlier in this report, the first step in the diagnosis of breast cancer usually is the discovery of a suspicious lump, either by a woman's physician during a routine physical examination or by a woman herself. In either case, the initial medical care is likely to come from the woman's private physician. That physician might be a general or family practitioner, an internist, an obstetrician/gynecologist, or another medical specialist. The physician is likely to refer the patient to a surgeon for clinical evaluation and possible recommendation to a radiologist for diagnostic mammography. If mammography reveals an abnormality, a biopsy might be required for definitive diagnosis. The biopsy may be performed by needle aspiration or surgical excision. Nurses, radiological technologists, and a variety of medical assistants participate in providing these services.

Recently, there has been increasing attention on the value of breast cancer screening for asymptomatic women. The purpose of screening is to detect the disease in its earliest stages, when treatment has the best chance of success. Most women are referred for screening mammography by their

physicians, based on age or other risk factors, but some women seek screening on their own. In a screening program for asymptomatic women, physical breast examination and the standard two-view mammographic examination would be followed--if indicated by questionable findings--by referral for more comprehensive diagnostic mammography. Confirmation of abnormal findings would then prompt referral to a surgeon for evaluation and possible biopsy to reach the diagnosis.

In the United States today, most medical services for breast evaluation are devoted to the diagnosis of breast cancer in women with symptoms rather than to large-scale screening programs. The most widely used breast imaging techniques are screen-film mammography and xeromammography; other methods that may be used include ultrasound, thermography, transillumination, computed tomography scanning, and magnetic resonance imaging (NCRP, 1986; "Health Technology," 1987a). Breast screening programs, designed to identify unsuspected breast abnormalities in asymptomatic women, may offer several of these imaging techniques. Many are limited to mammographic examinations, with or without on-site physical examinations and training in breast self-examination. For diagnostic evaluations of suspicious mammograms patients are usually referred to more comprehensive facilities. Most breast cancer screening and diagnostic services, including biopsy, are provided on an outpatient basis in any one of the following: hospital-based outpatient departments, ambulatory surgery centers, free-standing multispecialty clinics, or private physicians' offices.

The American Cancer Society (ACS) and the American College of Radiology (ACR) recommend mammography as the only imaging technique that is effective for breast cancer screening ("Health Technology," 1987a). Both ACS and ACR strongly recommend clinical breast examination in conjunction with any imaging technique, as well as continuing efforts to train women in breast self-

examination. It is well documented that mammographic screening is the best single method of detecting pre-clinical breast lesions: "The use of mammography alone has resulted in cancer detection rates of 33 percent to 59 percent higher than those provided by physical examination alone, by other imaging alone, or by a combination of techniques" ("Health Technology," 1987b). Mammography does not detect all lesions--from 8 to 15 percent of masses, including some large enough to be felt, may be missed by mammography (Homer, 1985; Kopans, et al., 1984)--but it is considerably more accurate than physical examination by patients or health professionals. A 1985 study of the ability of 80 physicians to detect lumps in a breast model found that the physicians detected only 44 percent of the lumps (Fletcher, cited in Castleman, 1986), and the sensitivity of breast self-examination may be less than 50 percent (Health and Public Policy Committee, 1985).

Since the 1970s, the trend has been to perform breast examinations using equipment specifically designed for mammography instead of general-purpose radiographic equipment. These specialized or dedicated mammographic machines are of two types: screen-film mammography and xeromammography. Both methods employ ionizing radiation but the doses of radiation are much reduced from levels common in the 1970s, when concerns about long-term low-dose radiation exposure from mammography were a significant deterrent to screening asymptomatic women ("Health Technology," 1987a). Modern screen-film mammography has developed such improvements as high-detail intensifying screens, enhanced film sensitivity, automatic processing, the use of breast compression devices, and the use of grids to reduce the amount of scattered radiation (NCRP, 1986, Paulus, 1987).

In xeromammography, x-ray images are recorded by xerographic techniques rather than by x-ray film. The Xerox Corporation introduced its first xeromammography machine in 1971. The standard powder-development xerography

process may be replaced in the future by a more sensitive liquid developing process (available in 1985), which produces a better image at half the radiation dosage. The greatest advantage of xeromammography is image edge enhancement, which allows the visualization of fine calcifications. Detection of poorly defined breast masses, however, is more difficult in xeromammography.

After a detailed comparison of screen-film mammography and xeromammography, the National Council on Radiation Protection and Measurements (NCRP) concluded that both techniques are efficient and effective. There are differences in terms of image characteristics, but "neither xeromammography nor screen-film mammography possesses an inherent imaging advantage." NCRP found that user experience with one technique or the other usually affected preference (NCRP, 1986; Paulus, 1987). However, xeromammography machines do not allow the high volume permitted by screen-film mammography. On the other hand, the maximum volume that can be achieved in the high volume screening programs discussed below would probably not be able to be achieved in any one particular program using xeromammography.

Breast Screening Services May Be Underutilized

At present, there is no evidence of a shortage of breast imaging resources in the United States. On the contrary, perhaps mammography services are currently underutilized. The ACS/ACR guidelines for mammographic screening are widely accepted among medical researchers and specialists, but screening mammography appears not to be standard medical practice. A Gallup poll for ACS in February 1987 found that only 15 percent of American women over 50 have annual mammograms, as the guidelines recommend (ACS, 1987). Another source has cited lower figures: In one study, only 5 percent of women over 50 had had annual mammograms, and only 33 percent of women over 50 had ever had a mammogram (including those referred for diagnostic purposes)

(Vinocur, 1986). A study of claims data from the Rand Health Insurance Study found that preventive care in general was provided infrequently; only 2 percent of women aged 45-65 received mammography as a preventive measure at least once in 3 years; and no women had yearly mammograms (Lurie et al., 1987).

Preliminary findings of the 1985 National Health Interview Survey conducted by the National Center for Health Statistics, U.S. Department of Health and Human Services, indicated that 45 percent of all women had a pap smear within the previous year and 50 percent of all women had a breast examination by a health professional. However, among women 65 and older, only 24 percent had a pap smear and only 38 percent had a breast examination during the year preceding the survey. Women covered by medicare were also less likely than younger women to know about breast self-examination and perform it regularly (USDHHS, PHS, NCHS, Advance Data, 197/87).

Data sources in the Health Care Financing Administration (HCFA) reported that in 1985, the Medicare program paid for about 753,000 mammographic examinations. These exams included services for women eligible for Medicare on the basis of disability (constituting about 6 percent of the female Medicare population) as well as women aged 65 and older. Thus, of the 17 million women aged 65 and older in 1985, only about 4 percent had a mammographic examination paid by Medicare. It is assumed that most of these mammograms were diagnostic procedures, because Medicare does not reimburse for most preventive services, including screening mammography.

Why Breast Screening is Underutilized

Screening mammography is not more widely used for the following reasons: 1) relatively few women are referred by their physicians for screening mammography; 2) fears about excess radiation exposure during mammography were raised in the 1970s and persist despite the prevalence of new, lower dose equipment; and 3) mammography is not covered by insurance (including Medicare) for screening purposes, and thus is relatively expensive. Fear of breast cancer may also deter some women from seeking timely screening and diagnostic services.

Low Rates of Referral. This apparent reluctance by physicians to refer their female patients for mammographic screening is, perhaps, the most troublesome factor in the present underutilization of breast screening. Another reason for nonreferral, in addition to the concern about radiation exposure discussed earlier in the report, may be that many primary care physicians are unaware of the ACS/ACR screening mammography guidelines. In 1985, only 55 percent of 306 family practitioners knew of the latest ACS guidelines, according to one study (Groveman, et al., 1986). A second survey of physicians' practices indicated that 80 percent of physicians follow ACS guidelines for breast physical examination, but only 3 to 17 percent refer patients for mammography on a regular basis (Anonym., 1985; Bassett, et al., 1986 Fox, et al., 1985). Other physicians who are aware of the guidelines seem not to believe that mammography is sufficiently effective in detecting early-stage breast cancer to justify the referral: 89 percent of Los Angeles County physicians in the survey mentioned earlier in this report did not refer asymptomatic women over 50 for mammography for this reason (Bassett, et al., 1986). In spring 1987, ACS reported a recent survey of attitudes and practices of primary care physicians in cancer detection that indicated only 49 percent of physicians ever recommended screening mammography in

asymptomatic women; only 11 percent follow or exceed ACS guidelines for mammography, but more than 95 percent of the physicians said they perform breast examinations and teach breast self-examination (ACS, 1987).

Costs of Screening Mammography. Finally, the cost of screening mammography and the fact that it is not reimbursed by most insurers is frequently cited as a factor in low use (ACS cited in "Health Technology," 1987a). Physicians say the cost of screening affects their referral decisions, and charges of $75 to $200 when paid out-of-pocket would deter many patients. In a study reported in 1983, 44.6 percent of all women referred for mammography from a breast cancer screening project complied with the referral: "Significant relationships were found between compliance and the self-reporting of breast symptoms, the physical findings on physical examination, and the source of payment for mammography. . . . Compliance rates ranged from 7.6 percent for women who were asymptomatic with normal examination findings and who had to pay for mammography to 92.5 percent for women who were symptomatic with abnormal findings who had mammography free of charge" (Lane and Fine, February 1983). In both symptomatic and asymptomatic women, compliance with referral for mammography was "significantly greater" when the examination was free. However, the study also cited public awareness of radiation hazards as a possible factor in noncompliance (Lane & Fine, 2/83).

As screening programs described later in this section indicate, it is possible to provide screening mammography for fees much lower than today's rate, that is, in the range of 30 to $50 per screening. The State of Maryland requires Medicare supplementary ("Medigap") insurance policies to reimburse policy-holders up to $100 annually for screening mammography, and some health maintenance organizations include screening mammography among their benefits (Brozan, 1986).

Although the several studies cited earlier have reported different

results, it appears that for whatever combination of reasons, as many as 90 percent of physicians do not now recommend screening mammography to asymptomatic women ("Health Technology," 1987a). This low referral rate must be considered the major deterrent to greater use of the service. Factors that may help overcome this obstacle include the somewhat greater receptivity to screening among younger physicians, growing awareness among women about the values of screening (which can encourage physicians to refer or may lead to increasing self-referral), and high-visibility national educational campaigns such as those sponsored in 1986 and 1987 by the American Cancer Society and its 58 local chapters ("Health Technology," 1987a: ACS, 1986, 1987).

## What Would Be the Resource Effects of Breast Screening Delivered According to ACS/ACR Guidelines?

It is clear that if ACS/ACR guidelines were the standard of care in breast cancer detection, the number of women referred for and seeking screening would increase dramatically. The National Cancer Institute recently endorsed large-scale mammographic screening for women over 50, recommending that the proportion of women between the ages of 50 and 70 receiving annual mammography should increase from the current level of about 15 percent to 80 percent (ACS, 1987).

In response to calls for more screening, doubts have been expressed about the ability of the health care system to meet potential demand. A January 1986 "Sounding Board" piece in the New England Journal of Medicine (Hall, 1986) is an example of these concerns: "The fully implemented ACS/ACR recommendation would require yearly mammograms for almost 50 percent of adult women--eight examinations per radiologists per working day!" Another study of the feasibility of mass breast screening, however, concluded that radiologists could accommodate greater demand without difficulty by examining 12 women

daily (Moskowitz, 1986). The demand on surgeons for the increased numbers of biopsies that would inevitably result from increased mammographic screening also would be substantial.

The possibility of a sudden explosion in demand for screening mammography, which probably would result from a Medicare reimbursement for the services, raises concerns about the availability of facilities and equipment to provide these services and especially about the availability of qualified health professionals. Mammograms are technically difficult to interpret; radiologists need special training and experience for proficiency (NCRP, 1986; Hall, 1986), and radiological technologists also require special training in mammography. Therefore, it is useful to try to anticipate the potential resource effects of expanded mammography screening for the Medicare population.

The computerized model of breast cancer screening for the Medicare population reported in this study was developed to help health planners "estimate the impact of different cancer control programs on the incidence, prevalence, mortality, prevalence of risk factors, and cost of different cancers and cancer control programs in future years" (Eddy, 1986). The model incorporates current knowledge about breast cancer prevalence by age group, stage at diagnosis, treatment modalities and costs, and outcomes, to project the overall costs and results in lives saved by implementing a Medicare breast screening program. An interim product of the model is the number of mammographic screenings that would be needed if all or any proportion of eligible Medicare women were to be screened each year from 1990 through 2020 (see Table 17). These figures will be used to estimate the effects of various levels of increased demand for mammographic screening in the Medicare population on present and future screening resources.

In addition to the effects on resources that would result from increased

screenings, the consequences on the demand for other services required to reach a diagnosis of breast cancer will be considered. As a result of screening, it can be expected that there will be increased demand for diagnostic mammmographic work-ups of uncertain exams, for mammographic localization of lesions in preparation for biopsy, and for the services involved in performing and analyzing biopsies. The proportions of abnormal findings that can be expected in a given population are relatively predictable, and so can be considered in estimating the effects of increased screening on resource use. For example, Sickles and colleagues report that in a population of asymptomatic women, 90 percent will have normal examinations (Sickles' response to letters, 1986).

For this analysis, it is assumed that in order to meet much greater demand for mammographic screening, the bulk of the services would be provided in programs specially designed for large-scale, low-cost breast screening of asymptomatic women. These screening services would be streamlined considerably compared with the comprehensive evaluations performed in diagnostic mammography. Largely to keep fees low, there has been a recent trend toward ambulatory health services of all types. An American Hospital Association survey, for example, found that 80 percent of 2,200 responding hospitals planned to expand ambulatory services, and 26 percent of these hospitals planned women's health clinics specifically for expansion (Hospitals, 2/5/87). Most breast screening programs now being developed are in non-hospital settings, such as freestanding multispecialty clinics, comprehensive women's health centers, specialized breast screening centers, private radiologists' offices, and even mobile units.

Low-Cost Breast Screening Programs

The potential for developing low-cost breast screening programs is greatest in non-hospital settings. According to the experience of a new,

Table 17.--Summary of Estimated Resource Requirements in 1990 to Provide Annual Breast Cancer Screening to American Women 65 and Older with Adjustment for Geographic Distribution of the Population[1]

| | | Mammography Component | | | BPE[2] Component |
|---|---|---|---|---|---|
| | Number of Examinations | Number of Examinations[1,3] | Number of Radiological Technologies[4] | Number of Radiologists[5] | Number of Health Professionals Qualified to Perform BPE[6] |
| If 30% of women 65-74 accept screening (base case) | 2,773,000 | 463 | 1,389 | 58 | 1,733 |
| If 100% of women 65 and older accept screening (maximum requirement) | 17,427,000 | 2,323 | 6,970 | 290 | 10,900 |

1 To adjust for the geographic dispersion of the population aged 65 and over (approximately 26% rural), we multiplied the number of machines and health professionals required to perform BPE by a factor of 1.25.

2 Breast Physical Examinations.

3 Assumption is that one mammography machine performs approximately 30 examinations daily or 7,500 examinations a 250-workday year.

4 Each mammography machine is operated by a staff of three radiological technologists (or similar staff).

5 Assumption is that screening mammograms can be interpreted by radiologists at the rate of approximately 30 per hour: that is, the average daily output of one mammography machine, 30 examinations, can be interpreted in 1 hour of a radiologist's time, or in 12.5 percent of a radiologist's 8 hour day. Put more simply, the number of machines divided by 8 gives the number of radiologists required to meet the assumed demand.

6 Calculation: 2,773,000 breast physical examinations divided by 8 per day = 347,000 person days, divided by 250 work days per year, = 1,386 health professionals. This number was then multiplied by a factor of 1.25 to adjust for the geographic distribution of the population, and rounded. 17,427,000 exams divided by 8 per day = 2,178,375 person days, divided by 250 work days per year = 8,714 health professionals.

voluntary membership organization called the National Consortium of Breast Centers, programs specializing in only screening mammography are being developed more rapidly than comprehensive breast diagnosis and treatment centers, because limited-service breast screening programs are substantially less costly to establish, staff, and operate (Rabinowitz, 1987). A number of specially designed low-cost breast screening programs already have been reported. Among them are the following examples:

- Richard E. Bird and Robert McLelland, "How to initiate and operate a low-cost screening mammography center," in Charlotte, North Carolina (Radiology, vol 161 no 2 pp.43-47, October 1986);
- Edward Sickles and colleagues, a mobile mammography van developed by the Department of Radiology, University of California School of Medicine, San Francisco, "Mammographic screening: How to operate successfully at low cost" (Radiology, July 1986); and
- Philip Strax described the Guttman Breast Diagnostic Institute, New York City, in "Mass Screening for Control of Breast Cancer" (Cancer, 53:665-670, 1984).

Bird and McLelland. Bird and McLelland began planning their low-cost mammographic screening facility in Charlotte, NC, in April 1985. The facility opened in August 1985 with one mammography machine and by late 1986 was screening 45 women daily at a charge of $27 per exam (two views per breast). The average price for mammography in Charlotte at that time was about $60.

Bird and McLelland's article in Radiology provides a useful, detailed guide for the development of similar screening mammography programs. They discuss such subjects as program planning, facility and equipment, steps to take before opening, program operations, film interpretation and reporting, promotion, and follow-up. The streamlined program was carefully designed to provide high quality screening at the lowest possible cost. Therefore, it

performs screening mammography only; it offers no physical examinations, no diagnostic mammography services, and no other breast imaging techniques. As noted earlier, both ACS and ACR recommend breast physicial examination in conjunction with mammography. Where and by whom the physical examination is performed for women using screening services appears to vary with the organization of the screening program. Because most screening mammography results from physicians' referrals (about 80 percent of the patients at this facility), the Bird and McLelland program does not provide physical examinations or instruction in breast self-examination, although a videotape on self-examination runs in the waiting room. The program accepts self-referred women, but these women must provide the name of a physician to receive the results and ensure appropriate follow-up. Pre- and post-screening services are not included in this facility's low charge, which would increase the total cost of screening for the patient.

The Bird and McLelland's program was planned around the capacity of one screen-film mammography machine to examine 40 patients per day, or about 10,000 patients per year. Only 600 to 800 square feet was needed to house the single mammographic unit and the staff of three radiological technologists, who rotate every 2 to 3 hours among the jobs of scheduling appointments, checking patients in and out, performing the mammograms, escorting patients, and processing films. The program, which encourages but does not require appointments, has found that scheduling patients at 10-minute intervals allows adequate time. There is no secretarial or billing staff: patients fill out their own forms, and fees are collected at the screening (the receipt includes all information necessary for the patient to file for insurance reimbursement).

The mammograms are interpreted at the end of each day by one or more radiologists, who are paid $10 per exam. The radiologists can interpret 20 to

30 exams an hour. The results of screening are reported to patients on postcards at the same time that full mammography reports are sent to their physicians. If results are abnormal, the physician also is contacted by telephone to ensure follow-up. The program has arrangements with local pathology departments to obtain the results of follow-up exams and biopsies for the patients it screened, for purposes of quality control.

The University of California, San Francisco, mobile van mammography screening program reported by Sickles and colleagues is similar to the North Carolina program in several respects. The objective of the specially designed, streamlined program is to offer screening mammography to asymptomatic women at low cost. Although the program's cost-effectiveness when screening a minimum 15 patients daily at $50 per patient has been challenged by other radiologists (see letters to the Editor of Radiology, December 1986, from Ronald G. Evens, M.D., St. Louis, MO, and from Ferris M. Hall, M.D., Boston, MA), Sickles has defended his costs. In order to operate efficiently at low cost, screening programs must exclude diagnostic workups. This, in Sickles' view, is the essential difference in the two types of programs. Because diagnostic mammography generally requires a radiologist to be on-site to interpret films while the patient waits in the mammography suite, and usually requires physical examination at the same time as mammography, a thorough diagnostic workup is a more detailed and time-consuming service than screening (and, hence, more expensive).

Once the patient population has been limited to asymptomatic women and the service to mammographic screening, Sickles describes other steps that can minimize costs: 1) limit the examination to two standard views per breast; 2) use a screen-film mammographic unit so that all films can be batch-processed at the end of the day; 3) computerize all records of the screening program to avoid paperwork and filing; 4) have radiologists interpret films in one daily

batch, using "canned" normal and abnormal reports that can be generated automatically by computer; and 5) require payment from the patient at the time of examination. Abnormal reports require individualized attention, and in such cases Sickles recommends a telephone call to the referring physician in addition to the written report. These efforts are intended to overcome potential communication problems between the screening program and the physicians who will be responsible for appropriate follow-up care. Radiologists in the Sickles program were able to interpret mammograms at a rate of 45 seconds per case and were willing to accept for a fee of $5 per exam.

An additional cost-saving feature of the San Francisco screening program is the use of a mobile van. A 34-foot recreational vehicle was customized to provide four rooms for use by three radiological technologists who, like staff of the North Carolina facility, rotate in the various jobs. The mobile facility was also found to make screening more convenient by reducing patient travel-time and encouraging screening during lunch breaks or after work, for example. Most of Sickle's screening patients had never had a mammogram before, so the program apparently was filling a gap in health care services.

The program decided to examine only referred women in order to minimize opposition from other providers. Like the North Carolina program, therefore, the San Francisco screening program did not provide physical examinations or consultations on site, because those services were provided by the referring physicians (presumably at additional cost to the patient or her insurer). The total costs to patients for complete screening services (physical examination, referral, mammogram, and consultation about results) were, therefore, higher than costs of the screening mammogram alone.

<u>The Guttman Breast Diagnostic Institute.</u> The Guttman Breast Diagnostic Institute in New York City, established in 1968, is among the oldest and best-

known breast screening programs. The objective of the institute was to develop a mass screening approach that would be feasible and widely acceptable, and it has since been used as a model for other mass screening programs in the United States and abroad. A report by the Institute found that screening could be made more economical by using specially trained paramedical personnel for many services. Non-physicians, for example, can perform competent physical examinations, and radiographic technicians can prescreen mammograms efficiently, thus saving radiologists' time. The mammographic examination itself can be automated to some extent to cut costs. The report also cited the advantages of mobile breast-screening units for efficiently reaching low-income populations. The cost of a complete screening examination at the Guttman Institute--including mammography, a clinical examination by a physician, BSE instruction, and a re-evaluation in suspicious cases--is currently $45 (Strax, letter to OTA, 9/18/87).

The Strax Breast Cancer Detection Institute in Fort Lauderdale, Florida, where about 25,000 women are examined every year follows essentially the same program as the Guttman Institute at a charge of $35.00 per screen.

Other examples of low-cost breast cancer screening programs. In the Washington, D.C., area, a newly-established, low-cost breast-screening program was recently advertised in newspapers. This program provides an example of how screening mammography services can offer a range of local variations while adhering to the general principles described above. The Washington-area program is a joint-effort by a hospital radiology department and a private radiology group. The screening program does not have its own facility or equipment; therefore, it operates two mornings a week in the radiologists' offices and two evenings a week (after regular hours) at the hospital's women's health center. Thus, low-cost screening patients are scheduled in off-hours at both locations. The hospital center schedules 15 patients per 8-

hour period for one mammographic machine; the private office schedules 25 patients per 8 hours for another machine. The hospital's part of the program is staffed by a receptionist and one radiological technologist.

At present, as the program is starting up, each location is doing about 20 screening mammograms a week at $65 per screen. Patients pay at the time of examination and receive a receipt for insurance reimbursement. In May, the program had patients booked through the end of June. The program takes physician- and self-referrals, provides mammographic screening without physical exams, and sends results to physicians and patients within two days (personal communications with staff of the Mary Esther Center for Women, May 1987).

The D.C. Government Department of Public Health also sponsors a mammography screening program, which uses a local hospital to provide up to 50 mammograms a month to women who do not have health insurance to pay for the service. To be eligible for the program, at least one of the following conditions must apply: women must be over 30 years of age with a family history of breast cancer, between 35 and 50 with no previous mammogram, or over 50 without a mammogram during the past year. In addition, she must be referred by a District Public Health Clinic (Advertisement, Washington Post Health section, June 16, 1987).

In 1986 and early 1987, the American Cancer Society sponsored a major breast-screening educational campaign. Several low-cost screening demonstration programs were implemented in 1986, and in March and April 1987, ACS issued news releases about its National Breast Cancer Detection Program and Breast Cancer Awareness Program. Educational activities were designed to reach physicians as well as the general public. The 58 ACS chapters distributed flyers, enlisted the media for free publicity, and organized special low-cost screening programs ($25 to $60) time (ACS, 1986, 1987). (A

summary of special ACS breast cancer awareness and screening activities by state and lists of low-cost screening sites distributed by Washington-area ACS chapters appear in Appendix C.)

ACR Mammography Accreditation Program

The American College of Radiology is accepting applications for accreditation in its new Mammography Accreditation Program. As of June 1987, more than 500 organizations had requested application materials (Zinninger, 1987). The purpose of this voluntary program is to provide quality assurance and education about equipment, dosage, and staff qualification standards. As background to this accreditation process, ACR and ACS support (with minor modifications) the principles described in the National Council of Radiation Protection and Measurement's "Mammography--A User's Guide" (NCRP, 1986). In addition, they agree that mammography is one part of breast evaluation, and history-taking and physical examination also are necessary. Therefore, a mammography program should provide these services directly or ensure that they are provided by the referring physicians. In addition, ACR has adopted its own minimum performance guidelines for mammography, which include the following points (ACR, 1986):

1) "Mammography is to be performed in a radiologic facility under the direct control of a radiologist who is board certified by the American Board of Radiology and has training in mammography. The technologists should be certified by the American Registry of Radiologic Technologists or equivalent state licensing body and have special mammography training."

2) "Mammography should be performed only on dedicated equipment."

3) "There should be an adequate device for compressing the breast."

4) "The mammography unit should be calibrated by a qualified radiation physicist at the time of installation of the equipment and then at least annually."

5) "An adequate quality assurance program should be in place that examines the equipment, film quality, and developing criteria, etc."

6) "The tube material, focal-spot size and filtration should be chosen appropriately for the characteristics of the image receptor."

ACR accreditation requires an applicant to complete a seven-page questionnaire (see Appendix D to this staff paper) with details on the type of mammography practice setting (private office, hospital, multispecialty clinic, mobile unit, multiple settings, other); other breast imaging services provided; physician certification and experience in mammography; training and certification of technicians performing the mammograms; detailed data on all mammographic equipment (manufacturer, model, dedicated or not, year installed, and technical characteristics); quality assurance program; contents of medical history taken; physical examination; and reporting mechanisms and ensuring follow-up. The accreditation process does not include standards of equipment capacity, efficient utilization, or costs.

Applicants who meet questionnaire criteria then purchase a designated breast phantom to provide image quality tests for the accreditation process and for use in an ongoing quality assurance program. Successful applicants will be accredited for three years. The American Cancer Society will list ACR accredited programs in its referral directories, and it is anticipated that ACR accreditation will become the standard for quality in mammography centers.

Conclusions on How Large-scale, Low-cost Mammography Screening Services Would Be Provided

If Medicare were to extend coverage to screening mammography, it is likely that a variety of delivery-program designs would be developed to meet increased demand. The actual configuration of the programs would vary to accommodate local circumstances and patterns of care. The Bird and McLelland low-cost screening model in Charlotte, NC, for example, probably would not be

transferrable to a large urban area with the same low operating costs (especially for facility space and staff salaries). The full range of potential variations in mammography screening program operations cannot be foreseen at this time, and in any case such variations are not critical to the overall analysis. Taking the Medicare End-Stage Renal Disease (ESRD) Program as an example, it can be expected that a decision by Medicare to reimburse for screening mammography services will stimulate providers to test and refine a variety of delivery patterns capable of providing a high volume of services at low cost.

Based on the programs described earlier, and taking into account the standardizing effects of the ACR mammography accreditation program, it is likely that large-scale, low-cost breast-screening programs in the future will have the following features in common:

- Most new breast screening programs will be developed in non-hospital-based outpatient settings--especially in free-standing, screening-only programs (including mobile programs) but also in diagnostic radiologists' offices, women's health centers, breast cancer diagnostic centers, and multispecialty clinics.
- The new programs will limit their services to mammographic screening only, with or without accompanying physical exams, and will streamline service delivery in a variety of ways to keep volume high and costs low.
- Screen-film mammographic equipment will probably be used in preference to xerographic equipment, because it allows batch processing and interpretation of films. But in either case, equipment dedicated specifically to screening mammography will be used, because it provides better image-quality at lower radiation dose, and it is more efficient.

- The maximum efficient screening capacity of today's basic delivery unit (one dedicated machine staffed by two or three radiological technologists, with one or more radiologists interpreting the films for a flat fee per exam) is an average 30 exams per 8-hour day, or about 7,500 exams per year. However, because of geographical dispersion of the target population, some centers may be likely to process fewer exams.

Projections of Demand for Screening Mammography

As reported elsewhere in this study, the computerized model of breast screening for the Medicare population generates the number of mammographic examinations expected in future years if eligible women are screened annually according to ACS/ACR guidelines. Table 17 summarizes the projected numbers of breast screening exams that would be demanded in 1990: (1) if 30 percent of women aged 65-74 are screened (i.e., our base case assumption), and (2) if 100 percent of women aged 65 and older actually are screened (i.e., the maximum requirement for aged Medicare beneficiaries).

In addition to the numbers of examinations that would be expected at different screening rates, Table 17 displays estimated numbers of mammographic machines, radiological, technologists, radiologists, and health professionals performing breast physical examinations (with instruction in BSE) that would be required to deliver the increased levels of demand. The bases for these estimates are as follows.

1) One screen-film mammographic machine has the capacity to perform an average of 40 screening exams per 8-hour day, or about 10,000 examinations a year (Bird & McLelland, 1986; Sickles, et al., 1986; and Zinninger, 1987). However, it is unlikely that machines at every center will achieve this volume because of geographic dispersion of the Medicare population. In addition,

centers with only one dedicated xeromammographic machine will not be able to do 40 examinations per day (Proctor, 1987).

In order to take into account the geographical dispersion of the target population, the estimates of the number of machines, radiological technologists and radiologists derived from the foregoing assumptions is multiplied by 1.25. This factor is derived from the fact that 25 percent of the female population 65 and older live in rural areas (U. S. Department of Commerce, Bureau of the Census, 1985). Note that an adjustment for geographic dispersion applied to machines also results in adjustments to the number of technologists and radiologists.

2) To perform 40 screening exams per 8-hour day in an independent, free-standing setting, each dedicated screen-film mammographic unit requires the support of three radiological technologists. In a facility with several dedicated machines, fewer than three technologists per machine would be required, because less skilled help could be substituted for technologists in some jobs. Staffing at three technologists per machine, therefore, represents a high estimate of future need (Bird, 1987; Sickles, 1987).

3) The need for radiologists with special training and experience in mammography to interpret films is estimated on the basis of 0.125 radiologists per machine (per day or per year). In the single-machine North Carolina screening program, a radiologist could interpret batched films at the rate of 20 to 30 per hour. In the San Francisco mobile van program, the radiologists completed one interpretation every 45 seconds, for a rate of 80 per hour. To be conservative and for simplicity in the calculations, it was assumed that mammograms could be interpreted by an experienced radiologist at the rate of 30 per hour. Thus, it would take no more than one a hour a day to interpret the mammograms generated in a breast cancer screening center. One hour of a radiologist's 8-hour day represents 12.5 percent of that day, or 0.125 of a

single radiologist's working time on a daily or annual basis.

3) To perform 30 breast physical examinations (with concomitant instruction in breast self-examination) in an independent, freestanding setting requires one physician, nurse, nurse practitioner, physicians' assistant or other trained allied health professional. This assumes 15 minutes per examination/instruction and an 8 hour day.

4) To take into account problems of geographic distribution of the screening capacity, which would contribute to the need for more centers operating at lower efficiency, we multiplied the number of machines and health professionals by a factor of 1.25. This factor was derived from the fact that about 25% of the female population age 65 and over live in rural areas (U.S. Dept of Commerce, Bureau of the Census, 1985). Note that an adjustment for geographic dispersion applied to machines also results in adjustments to the numbers of technologists and radiologist.

The above assumptions, applied to estimated future demand for mammographic screening in the female population aged 65 and older, produced the figures summarized in table 17. Furthermore, the requirements for equipment and staff should be understood as resources required for routine screening only, that is, resources in addition to those now devoted in the future to providing diagnostic mammography, mammographic localizations for biopsy, and other breast evaluation services. Finally, these screening resources represent demand in the Medicare population only, women 65 years of age and older, and other resources will continue to be required to provide the substantial volume of breast screening and diagnostic services that may be needed by younger women.

Although screening mammography for 30 percent of the female population 65-74 would represent about 2.8 million exams, compared with the 753,000 diagnostic examinations paid by Medicare in 1985--an increase of nearly 250

percent--the availability of resources to meet this greatly increased demand does not appear to be insurmountable. Future demand is linked to growth in the Medicare-aged female population, and this growth is expected to average 3 to 4 percent for each 5-year period from 1990 through 2020. Thus, gradual growth in the eligible population will allow time for resources to be developed to meet the increased demand, as long as the response to screening (the percent of eligible women actually screened) also grows only gradually over the period.

Whether increased demand could be accommodated by more efficient use of existing diagnostic and screening resources cannot be determined, because national data on current capacity are not available. Much of the demand could probably be managed in existing facilities by expanding hours, adding staff, and adding equipment if necessary. Operational means could also reduce the impact of a sudden increase in demand for screening mammography, which might occur if Medicare were to authorize reimbursement. For example, coverage might initially allow screening every other year, rather than annually, or use single-view examinations (as recommended for screening in Great Britain) (The Lancet, 3/7/87) instead of the two-view exams that ACS and ACR recommend. (Two studies comparing single- and two-view mammographic examinations, by Sickles et al. [1984] and by Bunnell et al. [1986], suggest that two-view screening is somewhat more effective than single-view.) By selecting individuals at higher risk of breast cancer for screening first, entry into the screening cycle could be controlled as resources are built up ("Health Technology" 1987a).

Estimates of Current Resources for Breast Cancer Screening and Diagnosis

Although the level and distribution of breast cancer diagnostic and screening resources available nationally are not known, there is no evidence of a current shortage. Instead, the low rates of women who actually are

screened and the need for extensive educational campaigns to encourage screening suggest that breast imaging services are underutilized. The American Cancer Society does not maintain a national inventory of these services, but many of the 58 chapters may do so. Sources contacted for this study indicated they were not aware of a current national inventory, and some suggested that such a list would be suspect because new centers are rapidly starting up (ACS, New York, 5/87; Zinninger, 1987). Response to the new, voluntary National Consortium of Breast Centers provides some evidence of that growth: 65 breast cancer centers were listed by the consortium as of January 1987, and in June, there were 90 centers. The directory cites the range of services, but not facility size or number of machines. Consortium staff estimate that 70 of the 90 centers provide breast screening services only, not comprehensive diagnostic and treatment services. Most of these facilities registered with the National Consortium of Breast Centers are located in major cites on the east and west coasts although the consortium has evidence that there are many diagnostic centers in the midwest (Rabinowitz, 1987; letter to OTA, 8/19/87).

In 1985, a Food and Drug Administration (FDA) NEXT (Nationwide Evaluation of X-Ray Trends) survey obtained lists of mammographic facilities from each state. FDA then complied a list of 3,939 facilities from the state inventories (these facilities may have had multiple mammographic machines). Today, according to the survey's director, there are probably more than 4,000 operating facilities--an increase inferred from the "skyrocketing sales" of new, dedicated mammographic equipment (Rueter, personal communication, 1987).

Another way to figure the level of screening resources is to estimate the number of units sold since 1980 or 1982. These units became the standard in the early 1980's recommended by ACS/ACR on the basis of lower radiation doses and improved image quality, replacing the multi-purpose radiographic

units used for mammography in the 1970s. One source at ACR estimated that at least 4,900 dedicated mammographic units are now operating in the United States (Zinninger, pc, 5/15/87)--far more than would be needed, according to Table 17, to accommodate the increased demand in screening by the Medicare population (assuming those resources are somewhat underutilized).

FDA has responsibility for monitoring radiographic equipment sold and installed in the United States. A form (Assembly Form 2579) must be submitted for each new piece of equipment installed. Although this form doesn't indicated whether the equipment represents new capacity, relocation, or replacement of an older unit, these forms give FDA an idea of the rapid rate of growth in new, dedicated mammographic equipment installations. FDA officials believe that compliance in filing this form is very good (95 percent or higher), because FDA has field surveillance capability to monitor equipment installations. Based on these forms, FDA reported the following numbers of mammographic installations in recent years (source: Charles Gunzburg, personal communications, 6/17/87, 8/13/87):

| | |
|---|---|
| 1982 | 134 units |
| 1983 | 326 |
| 1984 | 645 |
| 1985 | 1,621 |
| 1986 | 2,186. |

Clearly, installations of dedicated mammographic equipment have been increasing. This trend is substantiated by data reported to the National Electrical Manufacturers Association (NEMA), the trade association for manufacturers of mammographic equipment, representing about 80 percent of the units shipped. Five to six hundred firms are members of NEMA, including some foreign manufacturers and makers of both screen-film and xerographic units. The NEMA data system is not complete because sales data are reported on a

voluntary basis by NEMA members, and not all manufacturers importers are members. Sources at NEMA, therefore, say that FDA has the most accurate and complete figures, although NEMA'S figure are similiar to FDA's. NEMA reported 233 units shipped in 1983; 703 in 1984; 1,513 in 1985; and 1,572 in 1986 (Britain, 1987).

Trends in Future Resource Development

NEMA sources stated that if demand for screening mammography were to increase greatly in response to Medicare reimbursement, the production of mammographic machines could increase--perhaps three times current levels--without difficulty (Britain, 1987). There have been substantial technological improvements in mammographic equipment in recent years, and the technology will continue to improve. The focus of these improvements will be on better image-quality and reduced radiation dose. It is not likely that improvements in mammographic equipment would have important effects on equipment capacity (numbers of procedures per day), because capacity is primarily limited by the time needed to prepare and position the patients, not by the equipment itself (Britain, 1987). Improved image quality could result in fewer faulty or unreadable mammograms, however, which could reduce the number of repeat examinations required.

The availability of qualified medical staff to deliver the possible increase in volume of mammographic services is more of a problem than the availability of equipment. If demand increases gradually, medical training programs should be able to keep up with it. Radiological technologists, for example, who would be needed the most, can be trained readily. The American Registry of Radiologic Technologists, a national organization of about 160,000 members, requires graduation from an accredited training program and an examination for certification. Training usually is completed in a 2-year post-high-school program sponsored by a hospital or college (which awards an

associate degree). There is no specialty certification in mammography, but mammography is one of the procedures included in all radiologic technologist training programs. Seventeen states and Puerto Rico require the American Registry of Radiologic Technologists' certification examination for state licensure (Hansen, 1987).

Recent studies of the U.S. physician supply indicate that there will be an overall surplus of physicians in the near future. Trends in medical staffpower vary somewhat by specialty, but if demand for screening mammography grows gradually, there will be time for physicians to reorient their choice of specialty. Data from the American Medical Association (AMA) on numbers of Federal and non-Federal physicians, by specialty, for selected years from 1965 through 1985 indicate that radiology (with its subspecialties in diagnostic and therapeutic radiology) has been a growing specialty area (see below) (source: AMA, Physician Characteristics, 1986).

| | 1965 | 1975 | 1985 |
|---|---|---|---|
| General Radiologists | 9,553 | 11,527 | 10,109 |
| Diagnostic Radiologists | 38 | 3,544 | 12,887 |
| Therapeutic Radiologists | 56 | 1,169 | 2,272 |
| Total | 9,647 | 16,240 | 25,268 |

The total number of board-certified radiologists has increased from 9,647 in 1965 to 25,268 in 1985 (more than 160 percent). The number of physicians specializing in diagnostic radiology alone has increased from 38 in 1965 to nearly 13,000 in 1985 and now exceeds the number of general radiologists. Numbers of diagnostic radiologists have almost doubled during each of the past 5-year periods between 1965 and 1985. Therapeutic radiology has shown greater than average growth during those same periods, but general radiology has remained stable at about 10,000. Anesthesiology has grown at above-average rates, but pathology and general surgery have experienced below-

average growth (AMA, 1986).

Preliminary projections to 1990 made by the Graduate Medical Education National Advisory Committee (GMENAC) in 1979 (cited in OTA, 1980) have turned out to be reasonably consistent with actual AMA figures by specialty through 1985. General radiology was expected to hold steady or decline gradually as radiologists specialized in diagnostics or therapeutics, both of which were projected to grow (especially diagnostic radiology).

A recent study by the General Accounting Office (GAO) reported that radiologists earn the highest average net income of all medical specialists, $150,800, compared with an average $140,200 for anesthesiologists; $127,000 for pathologists; and $113,200 for physicians in 1985 (U. S. General Accounting Office, 1986). The GAO study concluded that radiologists, anesthesiologists, and pathologists (three types of specialists who often work under contract for one or more hospitals) "had the highest financial return on their training" among medical specialists. These findings suggest that radiology will continue to be an attractive field for specialization.

Another approach to expanding the pool of medical personnel available to interpret mammograms would be to provide special training and experience for medical professionals other than radiologists, such as other physicians and radiology assistants ("Health Technology," 1987a). Some radiologists disagree with this approach, and ACR accreditation guidelines now call for mammography programs to be under the direct control of board-certified radiologists. There would also be legal liability implications if non-physicians were used to interpret mammograms; however, if experienced radiologists came to be in short supply, such an option could be considered. An in-depth review of the feasibility of large-scale breast screening for women of all ages in the United States, concluded that adequate numbers of properly trained physician and non-physician staff now exist to provide current demand, and it should be

possible to expand these staff resources if necessary ("Health Technology," 1987a).

Conclusions on Screening Mammography Services for the Medicare Population

At present, the specialized medical resources needed to provide screening mammography services are not in short supply. If demand for screening mammography did increase substantially, which could be the case if screening became reimbursable under the Medicare program, it is not likely that resource limitations would be a significant deterrent. Resources for screening mammography will probably grow in response to demand. Large-scale breast screening services for Medicare women would probably be provided through specially designed, streamlined outpatient programs that offer screening mammography only. Setting, staffing, operating policies, and costs would vary according to local resource availability and practice patterns, but most would seek to conform to ACR mammography accreditation standards. In addition to the development of new programs, existing programs could expand their capacity through more efficient operations. Finally, Medicare could require inclusion of screening mammography in the negotiated service packages provided through health maintenance organization contracts and other programs.

The Medicare End-Stage Renal Disease (ESRD) Program provides an example of the potential resource and cost effects of Medicare reimbursement policy decisions. When Congress in 1973 included most individuals with irreversible kidney failure in the Medicare program, which guaranteed Medicare beneficiaries coverage for the dialysis or kidney transplant services they needed to stay alive, relatively few beneficiaries were receiving dialysis services because of the high costs of chronic dialysis and the limited availability of costly equipment. There were approximately 16,000 program beneficiaries in 1974, and they were served at a cost of $228.5 million to the

Medicare ESRD Program (Mayhugh, 1987).

Once Medicare began to pay for dialysis services, however, resource development accelerated. New freestanding dialysis facilities opened outside the hospital units where dialysis services were first provided. New staffing patterns were developed that relied heavily on dialysis technicians with limited specialized training rather than on the physician and nursing staffs used in the hospital units. Physicians in internal medicine specialized in nephrology, and nurses also developed nephrology specialties. Technological developments reduced dialysis equipment costs and increased dialysis efficiency so that patient time connected to the machines was reduced.

There was a great incentive to develop efficient, low-cost dialysis services because Medicare established a flat reimbursement rate. Dialysis capacity expanded along with the patient population, and new capacity was designed to provide services efficiently, at reduced cost (at or below the Medicare reimbursement rate) and, thus, at some level of profit. The cost effects on the Medicare program have been considerable, because growth in the dialysis patient population has exceeded all predictions: by the end of 1986, more than 103,000 patients were covered by Medicare ESRD program at a cost of about $2.3 billion a year (Mayhugh, 1987).

It is apparent that capacity for screening mammography is already expanding rapidly, even without Medicare reimbursement (although anticipation of Medicare coverage may be having an effect). Many of the features that reduced the costs of dialysis services are being applied in the new breast screening programs: choice of an outpatient, free-standing setting; a limited range of services; innovative staffing arrangements to maximize use of non-physician staff relative to costly radiologists' time; operating practices designed to increase the efficiency of screening; and the replacement of old, all-purpose radiographic equipment with new, dedicated mammography units.

Analysis of Medicare reimbursement policies for screening mammography should take into consideration the Medicare ESRD program's experience with rate-setting. Based on the dialysis experience, it can be expected that costs-per-service will be higher when the service is new and will decline as more providers offer the service in programs that incorporate the cost-cutting features described earlier. Furthermore, costs may vary considerably by geographic region, urban or rural setting, and local medical practice patterns. For these reasons, it would seem unwise to guarantee Medicare reimbursement for breast screening services at a fixed rate, unless that rate were set very low--intended perhaps to cover only a portion of screening costs, e.g., $50 or less per screening, or a percent of charges, leaving patients to pay the remainder out-of-pocket or from other insurance.

Guaranteed coverage of screening mammography at any reimbursement rate is likely to contribute to higher costs to the overall Medicare program. For example, a large-scale breast screening program would increase the number of biopsies for apparent abnormalities discovered by the screening ("Health Technology," 1987a and Part III of this staff paper). Biopsies require substantial additional services, including radiological localization of the lesion, surgery, and pathology services; appropriate indications for biopsy and acceptable ratios of negative biopsies for each positive breast cancer appear to be subjects of debate. The risks of legal action in cases of failure to diagnose cancer provide pressure to perform more biopsies (more biopsies with lower chances of being malignant) rather than less ("Health Technology," 1987a).

Several model programs described in this section have demonstrated that it is relatively easy and inexpensive to develop efficient, low-cost breast screening programs. If programs can offer screening at low cost, many women will seek out the service with or without their physician's referral and with

or without insurance reimbursement. The American Cancer Society now supports self-referral for breast screening, and its nationwide educational campaigns in 1986 and 1987 are raising levels of awareness in the public and among physicians. A demand for low-cost breast screening already exists and it is likely to grow. This demand may already be high enough to encourage providers to develop more efficient screening services, priced so that most women can afford them.

The rapid expansion of new free-standing breast screening services is likely to raise concerns about the quality of the services provided. The ACR mammography accreditation program will establish quality standards because most screening programs will be designed for ACR accreditation to ensure listing by ACS. Medicare could decide to pay only for screening services provided in ACR-accredited facilities. Quality standards can contribute to increased service delivery costs, however, and limit opportunities for cost savings. On the other hand, even a relatively high reimbursement rate will not in itself guarantee quality of care. Quality monitoring should remain a concern, especially if facilities are not accredited or if several facilities are involved in price competition.

## Notes

[1] The number of new cases represents the number of new primary cases, and excludes second breast cancers in women previously diagnosed with breast cancer. The total number of new breast cancer cases in 1987 is expected to be approximately 130,000.

[2] The States of Maryland and Texas recently passed legislation requiring that so-called "Medigap" policies include coverage for screening mammography. In Maryland, insurers are required to reimburse up to $100 per screen per year. In Texas, insurers are required to cover mammography on the same basis as other radiological examinations.

[3] Federal Register, 52(103):20147, May 29, 1987.

[4] Anecdotal evidence indicates that some physicians who believe in the value of breast cancer screening may refer women for mammograms in the absence of any symptoms. If cost is an issue, the physicans may note that the breast physical exam and mammogram are diagnostic, so that the patient will be reimbursed.

[5] We also assumed that a medical history would be taken, and instruction in breast self-examination would be given along with the breast physical examination.

[6] This figure includes the possibility of additional mammograms, additional visits to consulting surgeons, surgery, and pathology. Most of these procedures are now conducted on an outpatient basis; in the Medicare population, however, a fair number are conducted on an inpatient basis, which is more costly.

[7] Defined as care delivered during the last six months of life.

[8] Examples include the deduction for hospital stays of about $500 per stay; the cost of prescriptions for hormonal therapy (tamoxifen), which locally costs about $2 per day (over a period of a year, a patient may have to pay $730); and the costs of psychological treatment to deal with the grief associated with loss of a breast and perhaps imminent loss of one's life.

[9] OTA's analysis does include a table showing charges submitted to Medicare as well as Medicare's reimbursements made on the basis of those charges, both as analyzed by NCI.

[10] Lurie, et al., 1987, in a study of data from the Rand Health Insurance Experiment. If annual mammograms are considered, the percentage is zero.

[11] Women over 50, annual mammograms (Vinocur, 1986).

[12] Women over 50, annual mammograms (American Cancer Society, 1987).

[13] Discounting is a procedure used in economic analysis to express as "present values" those costs and benefits that will occur in future years. Discounting is based on two premises: 1) individuals prefer to receive benefits today rather than in the future, and 2) resources invested today in alternative programs could earn a return over time. Source: U. S. Congress, OTA, Health and Life Sciences Division, Compilation of Acronyms

and Terms (Washington, DC: Author, August 1986.)
In theory, both life-years and costs can be discounted, but there is some disagreement about the validity of discounting health effects. In this analysis, only costs have been discounted. The effect of discounting life-years would double the cost per life-year saved.

[14] These proportions exclude unstaged cancers and errors.

[15] calculated as the average cost to Medicare incurred within the first three months of diagnosis by a woman with breast cancer ($5,730), minus the average cost for a comparable three-month period for a woman who does not have breast cancer ($439) (see Appendix B).

[16] calculated as the cost to Medicare per month of a woman with breast cancer ($349), minus the cost to Medicare per month of a woman without breast cancer ($166).

[17] Table 12 assumes the woman adheres to the screening protocol and is actually screened each year in the 10-year period.

[18] calculations based on comparison of the stage proportions observed in the BCDDP for women over age 50, and stage proportions in SEER (see Seidman, et al., 1987).

[19] This reduction in mortality was achieved by assuming the following stage proportions: stage 0, 0.05; stage I, 0.415; stage II, 0.44; stage III, 0.095; stage IV, 0.

## Appendix A

### Calculation of Estimated Cost to Medicare of a Diagnostic Workup for Breast Cancer

| | | |
|---|---|---|
| **Outpatient (medium estimate[1]):** | | |
| Bilateral mammogram (76091)[2] | $45.[3] | |
| done on xerox equip. (76150) | 29.[4] | $ 74. |
| Physician visits 2 @ $31[5] (90815) | | 62. |
| Incisional biopsy (19101) | | 170.[6] |
| Pathology (88304) | | 30.[7] |
| Facility | | 275 |
| Total - lower estimate | | $ 611 |
| **Outpatient (higher estimate including cost for diagnostic mammogram with radiologic marker):** | | |
| Outpatient lower estimate (from above) | | $ 611. |
| Cost for diagnostic mammogram with radiologic marker (76096) | | 46.[8] |
| Total - higher estimate | | $ 657. |
| **Inpatient (low estimate): (Frequency = 2,870)** | | |
| Hospital charge (ICD-9 Code 85.12) | | $3,025.[9] |
| Office physician visits 2 @ $31 | | $ 62. |
| Hospital physician visits 6[10] @ $31 | | 186. |
| Physician fee - biopsy (19101[11]) | | 170. |
| | | $3,443. |
| **Calculation of Average Cost of Biopsy:** | | |
| Sum of: | | |
| Proportion medium estimate outpatient (.88) * Cost to Medicare of medium estimate outpatient ($611) | | $ 538. |
| Proportion high estimate outpatient (.03[12]) * Cost to Medicare of high estimate outpatient ($657) | | $ 20 |
| Proportion inpatient (.89[13]) * Cost to Medicare of inpatient ($3,443) | | 310. |
| | | $ 868. |
| Rounded to | | $ 900. |

---

1A lower estimate would not include charge for xeromammography.
2 For outpatient charges, numbers in parentheses are CPT-4/HCPCS codes. CPT-4 Codes come from Clausen et al., 1984. HCPCS codes are the codes used by the U. S. Department of Health and Human Services Health Care Financing Administration to designate procedures paid for by Part B of Medicare. For the most part these codes are the same as the CPT-4 codes, and for the most part they are for outpatient care.
3 Derived by dividing the dollar amount for allowed charges ($31,470,470) by the number of charges submitted (the "frequency" in HCFA's terms) (691,962) in 1985. The Source was U. S. Department of Health and Human Services, Health Care Financing Administration, "1985 National Summary Table - BMAD Procedure File," Printout dated May 20, 1987.
Footnotes for subsequent categories indicate the allowed charges and frequencies only.
4 $2,442,697 divided by 85,128.
5 $67,006,561 divided by 2,178,980.
6 $3,856,986 dividided by 22,688
7 $66,967,763 divided by 2,228,738. Note that this code includes charges for pathology services for all diagnoses. CPT-4/HCPCS codes are procedure codes and are not specific to diagnosis.
8 $954,794 divided by 20,745.
9Source: U. S. Department of Health and Human Services, Health Care Financing Administration, C. Helbing, Letter to OTA dated .
10Average length of stay for an inpatient biopsy (U. S. DHHS, HCFA, C. Helbing, Letter to OTA dated 1987.
11See above.
12In 1985 Medicare allowed charges for 20,745 mammograms with radiologic markers. This figure was divided by the total of 691,962 allowed charges for bilateral mammograms.
13Medicare's Part A file shows charges for 2,070 inpatient biopsies. Medicare's Part B file shows charges for 22,688 biopsies.

## Appendix B

Medicare Reimbursements for Breast Cancer Treatment
Charges to Medicare for Breast Cancer Treatment

Charges to Medicare for Breast Cancer Treatment of Women 65 and Older

**SITE OF FIRST CANCER DIAGNOSIS = BREAST (ICD-9 code 174)**

**Charges for treatment during initial, continuing, and terminal phases of cancer.**
**For each record section within the Continuous Medicare History File.**
**Initial and terminal charges are per patient and are followed by the standard error of the mean in parentheses.**
**Continuing care charges are per patient month. All charges are adjusted to 1984 dollars.**

| CMHF Section | Cancer Phase | | | | |
|---|---|---|---|---|---|
| | Initial | Continuing | Terminal by Survival Time | | |
| | (N = 9452) | (N = 9452) | >= 9 months (N = 2780) | < 9 months (N = 1724) | Unspecified (N = 4504) |
| 1. Home Health Agency | | | | | |
| Part A | 26 ( 1.3) | 6 | 176 ( 11.5) | 127 ( 12.5) | 157 ( 8.5) |
| Part B | 4 ( 0.5) | 1 | 49 ( 5.6) | 26 ( 4.2) | 40 ( 3.8) |
| 2. Outpatient | | | | | |
| Outpatient Services | 114 ( 2.3) | 22 | 276 ( 11.1) | 232 ( 14.7) | 259 ( 8.9) |
| Inpatient Services | 1. ( 0.2) | 0. | 23 ( 6.9) | 4 ( 2.1) | 16 ( 4.4) |
| Other Services | 5 ( 1.7) | 1. | 31 ( 8.2) | 15 ( 6.7) | 25 ( 5.7) |
| 3. Payment Record Section | | | | | |
| Non-hospital Services | 672 ( 5.0) | 113 | 2221 ( 40.4) | 1896 ( 51.7) | 2097 ( 31.9) |
| Physician Services | 634 ( 4.8) | 95 | 1687 ( 37.2) | 1552 ( 47.0) | 1635 ( 29.2) |
| Surgical Services | 300 ( 2.5) | 32 | 390 ( 17.4) | 429 ( 18.8) | 405 ( 12.9) |
| Supplier Services | 29 ( 1.0) | 8 | 185 ( 8.8) | 117 ( 9.2) | 159 ( 6.5) |
| Hospital Services | 11 ( 0.4) | 2 | 51 ( 2.8) | 41 ( 3.0) | 48 ( 2.1) |
| Psychiatric Services | 0. ( 0.1) | 0. | 1. ( 0.2) | 0. ( 0.2) | 0. ( 0.1) |
| 4. Inpatient Hospital Stay | 5730 ( 51.4) | 184 | 9256 (230.1) | 12310 (289.8) | 10425 (181.5) |
| 5. Skilled Nursing Facility Stay | 80 ( 6.3) | 18 | 791 ( 49.8) | 504 ( 45.6) | 681 ( 35.4) |
| TOTAL | 7606 ( 58.1) | 483 | 15136 (301.9) | 17256 (380.1) | 15948 (236.9) |

Source: NCI.

Medicare Reimbursements for Breast Cancer Treatment -
Initial, Continuing and Terminal Phases

SITE OF FIRST CANCER DIAGNOSIS = BREAST (ICD-9 code 174)

REIMBUR for treatment during initial, continuing, and terminal phases of cancer.
For each record section within the Continuous Medicare History File.
Initial and terminal charges are per patient and are followed by the standard error of the mean in parentheses.
Continuing care charges are per patient month. All charges are adjusted to 1984 dollars.

| CMHF Section | Cancer Phase | | | | |
|---|---|---|---|---|---|
| | | | Terminal by Survival Time | | |
| | Initial (N = 9452) | Continuing (N = 9452) | >= 9 months (N = 2780) | < 9 months (N = 1724) | Unspecified (N = 4504) |
| 1. Home Health Agency | 24 ( 1.2) | 5 | 160 ( 10.4) | 113 ( 10.7) | 142 ( 7.6) |
| Part A | 3 ( 0.4) | 1 | 42 ( 5.0) | 22 ( 3.4) | 35 ( 3.4) |
| Part B | | | | | |
| 2. Outpatient | 83 ( 1.8) | 16 | 200 ( 8.5) | 167 ( 11.0) | 187 ( 6.7) |
| Outpatient Services | 1. ( 0.2) | 0. | 17 ( 5.5) | 3 ( 1.7) | 12 ( 3.5) |
| Inpatient Services | 4 ( 1.3) | 1. | 23 ( 6.5) | 11 ( 5.2) | 19 ( 4.5) |
| Other Services | | | | | |
| 3. Payment Record Section | 421 ( 3.2) | 64 | 1179 ( 25.1) | 1065 ( 32.5) | 1135 ( 19.9) |
| Non-hospital Services | 403 ( 3.1) | 59 | 1066 ( 23.7) | 991 ( 30.4) | 1038 ( 18.7) |
| Physician Services | 189 ( 1.6) | 20 | 244 ( 10.9) | 270 ( 11.8) | 254 ( 8.1) |
| Surgical Services | 18 ( 0.6) | 5 | 112 ( 5.4) | 72 ( 5.7) | 97 ( 4.0) |
| Supplier Services | 7 ( 0.2) | 1 | 32 ( 1.8) | 26 ( 1.9) | 30 ( 1.3) |
| Hospital Services | 239 ( 2.6) | 35 | 469 ( 13.6) | 393 ( 16.0) | 440 ( 10.4) |
| Unassigned Totals | | | | | |
| 4. Inpatient Hospital Stay | 4309 ( 39.8) | 139 | 7016 (163.6) | 9464 (216.5) | 7953 (131.8) |
| 5. Skilled Nursing Facility Stay | 28 ( 3.0) | 3 | 213 ( 17.4) | 225 ( 22.2) | 218 ( 13.7) |
| TOTAL | 5730 ( 44.6) | 349 | 10776 (213.7) | 12824 (277.2) | 11560 (169.9) |

Source: National Cancer Institute, Division of Cancer Prevention and Control, unpublished data

Appendix C

American Cancer Society 1987 Breast Cancer Awareness Program

Division Activities

AMERICAN CANCER SOCIETY®

1 West 35th Street
New York, N.Y. 10001
212-736-3030

# NEWS SERVICE

## BREAST CANCER DETECTION AWARENESS PROGRAM, DIVISION ACTIVITIES

ARIZONA: A statewide mammography screening is planned in April and May (May 4-8, Phoenix; April 27-May 1, Tuscon). Radiological and breast health centers will be participating, using the ACS Cancer Response System toll-free number to schedule low-cost mammograms ($50-60). Between 5000 and 10,000 women are expected to be screened. CBS affiliates are co-sponsors of the project. CONTACT: Kathleen Kelly, 602/234-3266.

ARKANSAS: The program includes ACS Professional Education workshops, Public Education breast health programs, and a Public Information campaign in print and broadcast media. Campaign includes a five-part series on breast cancer to be aired on KARK-TV, Little Rock. CONTACT: Linda O'Neill, 501/664-3480.

CALIFORNIA: Using the theme "Smart Woman: She spents $50 for a bargain that saved her life," the ACS California Division and KPIX-TV, Channel 5, in San Francisco, will co-sponsor a low-cost mammography screening project April 19-24. A toll-free number will be manned 12 hours a day, informing women of the availability of low-cost mammograms ($50) and of other important facts related to breast cancer. All flyers, fact sheets, releases and PSAs are being translated into Spanish. CONTACT: Sheila Hennessey, 415/893-7900, or Emily Warden, 415/386-7660.

COLORADO: For the past four years, a statewide Breast Cancer Awareness Week has been held. In April, Breast Cancer Screening programs will be held at three sites in the state, a pilot project will offer low-cost mammograms ($65) and educational programs will be held in hospitals and businesses. The residential theme in April will be "Each One, Reach One," and a screening project for the medically indigent is planned with the Colorado Department of Health. CONTACT: Sue Kirkland, 303/758-2030.

CONNECTICUT: During Breast Cancer Awareness Week, April 20-27, radio and television stations statewide will be featuring ACS volunteers discussing mammography and other aspects of breast cancer detection. Public Education efforts include Breast Self-Examination Teach-ins at area hospitals, and in junior and senior high schools, health educators will conduct breast self-examination programs. CONTACT: Marion Gillotti or Dennis Randall, 203/265-7161.

DELAWARE: On April 4, a Breast Cancer Diagnosis and Management Update program will be conducted by the Division's Professional Education staff, featuring

-more-

a panel of distinguished physicians. Other programs planned include a Cancer Nurses Reach to Recovery Conference and in May, a Breast Cancer Screening program with area hospitals. CONTACT: Pam Finkelman, 302/654-6267.

DISTRICT OF COLUMBIA: In the metro-Washington area, 11 screening centers will offer low-cost mammograms ($25-75) to eligible women in an on-going breast cancer detection program. Last year's free mammographic screening involved more than 6500 women, and this year at least 3000 more are expected to be screened. In addition, a low-cost cancer screening ($15-30), including a manual breast exam, will be given at five sites in the DC-area. CONTACT: Lois Callahan, 202/483-2600.

GEORGIA: On Feb. 2, 3 and 4, WSB-TV in Atlanta aired a three-part series on breast, prostate and testicular cancer on the 6 p.m. news. Phones were manned by ACS volunteers to answer questions on these cancers and to give the locations of educational programs and low-cost mammograms ($50) being given at hospitals and clinics throughout the city. More than 2000 calls were handled by the volunteers and more than 1800 Atlantans attended the education programs. CONTACT: Curtis Allen, 404/892-0026.

HAWAII: The more than 8000 volunteers for the 1987 American Cancer Society Residential and Educational Drive will be offered low-cost mammograms ($25). The opportunity for the mammogram at a reduced cost can be transferred if a volunteer cannot use it him or herself. Six screening centers are participating in this program. By educating ACS volunteers about early detection procedures, volunteers can better describe such procedures during the educational campaign. CONTACT: Eleanor Waterhouse, 808/531-1662.

IDAHO: A five-county breast cancer awareness program will be conducted during March, April and May, with intensive media promotion May 4-8. Reduced-cost mammograms ($47-69) will be offered at participating centers, in addition to breast self-examination instruction and other educational programs. CONTACT: Pam Smith or Lee Fleming, 208/343-4609.

INDIANA: During Cancer Awareness Week, ACS guidelines on the early detection of breast cancer will be highlighted. In addition, more than 50 screening facilities statewide will provide mammograms at greatly reduced costs (free-$40). Between 5000 and 7000 women are expected to be screened during the program. CONTACT: Dave Francoeur, 317/872-4432.

LONG ISLAND: In cooperation with other ACS Divisions in the Metro-New York area, the Long Island Division will hold a Breast Cancer Detection Awareness program in May. The educational program will inform women calling the American Cancer Society of low-cost mammograms ($40) at 20 participating hospitals, where they will also receive a manual breast exam as well as breast self-examination training. CONTACT: Judy Scheinfeld, 516/385-9100.

KANSAS: Phase One of the Division's Breast Cancer Detection Awareness program is complete, with 300 women having received free mammograms and others having mammographic exams at reduced costs. All women screened were also given a physical breast exam as well as training in breast self-examination. This pilot project will now be expanded. For further information, CONTACT: Jeri Heycock, 913/267-0131.

MASSACHUSETTS: A statewide campaign entitled "Mammography: The Breast Test" will be conducted to educate people about early detection of breast cancer. The program begins in late April (21st-28th) when more than one million Massachusetts households will receive information on breast cancer during the residential Crusade. The following week (April 29-May 3) a toll-free number will be available for information on low-cost mammograms ($50 or less) at more than 100 hospitals throughout the state. The mammographic screening period is May 11-22, 1987. CONTACT: Karen Rouse or Karen O'Rourke, 617/267-2650.

MICHIGAN: A program called "Breast Screening '87: Give yourself the Chance of a Lifetime" will be held April 27-May 30 in the Detroit area. More than 41 organizations, including hospitals offering mammograms for $50, will be involved in the program. CONTACT: Laurie Homann, 313/425-6830.

MILWAUKEE: In co-sponsorship with the ACS Wisconsin Division, a statewide mammography screening will be held in May. At a cost of $50 or less, participating women will receive a mammogram, a physical breast exam and instruction on breast self-examination. CONTACT: Kim Gleason, 414/453-4500.

NEW HAMPSHIRE: During the first two weeks of May a Breast Cancer Detection program, to be announced during the April ACS residential program, will be conducted throughout the state. Participating hospitals and clinics will issue certificates for a low-cost ($50) mammogram, good for one year. CONTACT: Margaret Murphy, 603/669-3270.

NEW JERSEY: In conjunction with the programs of other ACS Divisions in the area, more than 50 hospitals statewide will provide education, physical examinations and low-cost mammograms ($40) to an estimated 10,000 women in May. CONTACT: Shirley Greene or Jeff Hall, 201/297-8000.

NEW MEXICO: From April 20 to May 1, KOAT-TV, Channel 7, in Alburquerque, and other local media, will promote a Breast Cancer Detection Awareness program. Through this ACS program, the public will be offered information on mammography and other aspects of breast cancer detection, in addition to low-cost mammograms ($45). More than 3000 women are expected to be screened through this program. CONTACT: Barbara Barnes Allen, 505/262-2336.

NEW YORK STATE: WIVB-TV in Buffalo is co-sponsoring a mammography screening program March 11-16 in 10 counties in western New York. Women can call in to receive a certificate for a low-cost mammogram ($35) to be redeemed at participating hospitals and clinics. The state's other 44 ACS Units will promote breast cancer detection awareness through educational programs during April. CONTACT: Peg Camp, 315/437-7025.

NORTH CAROLINA: The program will focus on the primary care physician as well as the public in increasing awareness of breast cancer detection. Physician examination, self-examination and low-cost mammograms (from $27-50 at 10-12 centers in the state) will be the three featured phases. CONTACT: Joni Brooks or John Postiglione, 919/834-8463.

OHIO: The Ohio program is a six-phase breast cancer dection project covering all major metropolitan areas of the state. To date, more than 4500 women

have been screened, and thousands more will participate as the program continues into 1988. Through the promotion and co-sponsorship of the programs by radio and television stations in each area, mammograms have been offered, ranging in cost from free to reduced costs of $33-45. CONTACT: Peg Rauckhorst, 216/771-6700, for an overview of the statewide program and for individual contacts in the six areas.

OREGON: Working with KATU-TV, Channel 2, in Portland, the Oregon Breast Cancer Detection Awareness Project will take place in May. Low-cost mammograms ($45) will be offered through 97 participating hospitals and clinics statewide. CONTACT: Bonny Groshong, 503/295-6422.

PENNSYLVANIA: In late March and early April a media campaign will alert the public to the availability of low-cost mammograms ($40). Women can return a coupon from the newspaper for information on these low-cost mammograms, available at various centers during the last two weeks of April. Other information on breast cancer detection will be provided through the Cancer Society. CONTACT: Ann Hopwood, 215/921-2328. For information on other Pennsylvania ACS breast cancer detection programs (not including Philadelphia), CONTACT: Deborah Medvick, 717/533-6144.

PHILADELPHIA: In 1986 a highly successful breast cancer screening was held in Philadelphia. Low-cost mammograms ($40) were offered by 62 area hospitals and clinics, screening more than 5600 women. The Division's hotline received more than 10,000 calls during the screening period, and 14 malignancies were detected. A similar program will be conducted in May 1987. CONTACT: Patricia LePera, 215/665-2936.

PUERTO RICO: A low-cost mammography screening ($35) is planned, with more than 1000 women expected to be screened. For details, CONTACT: Raquel Helfeld, 809/764-2295.

RHODE ISLAND: Beginning in June of 1987, a low-cost mammography screening program will begin, with a mammogram offered for $50. During this joint program with the Rhode Island Department of Health, more than 4000 women are expected to be screened. CONTACT: Nancy St. Germain, 401/722-8480.

TENNESSEE: Red Food Stores and hospitals statewide will co-sponsor a "Taking Control through Early Detection" program May 11-23. A quarter million coupons for low-cost mammograms ($50) will be distributed at all 49 Red Food Stores. CONTACT: Curtis Johnson, Red Food Stores, 615/892-8029, or Margaret Smith, American Cancer Society, 615/383-1710.

TEXAS: The Texas Breast Cancer Screening Project will take place in cities statewide in February, March and April, with 20 television stations co-sponsoring the program. Mary Kay Ash, Chairman of the Board of Mary Kay Cosmetics, is the state project chairman. The awareness/education/demonstration project is expected to screen more than 30,000 women, offering low-cost mammograms for $50 or less. During the first week of the project, in late February, ACS volunteers received more than 53,000 calls, 90 percent of which were from eligible women. The Dallas-Ft. Worth area joined the program on March 2. CONTACT: Tim Elsner, 512/928-2262.

UTAH: As part of the Division's Breast Cancer Detection Awareness Program, all hospitals and clinics with dedicated mammography units in the state are being contacted. Their cooperation in this program to provide low cost high quality mammogram screenings is being solicited. A statewide survey of individuals will also be conducted, during the April educational and residential campaign. In addition to educational literature distributed to every home visited in the campaign, 30,000 women will be questioned about their family history of breast cancer, their own breast cancer detection practices and other information related to breast cancer. During the statewide screening program, mammograms are expected to cost from $35 to $65. CONTACT: Lynn Meinor, 801/322-0431.

VIRGINIA: During February 1986, the Virginia Division conducted a highly-successful breast cancer screening program. During the two-week period of the screening, more than 13,000 calls were received on the breast cancer hotline. More than 12,000 eligible women registered, and almost 9000 received mammographic screenings. To date, 30 cancers were postively identified through the screening. For futher information on this on-going project, CONTACT: Gail Hudson, 804/270-0142.

WASHINGTON: The Cancer Society's statewide breast cancer detection program will promote toll-free phone lines for women to call for information about low-cost mammograms ($45). Almost 80 health care facilities throughout the state are offering the mammograms. Women who meet the requirements for the mammograms at a reduced rate are sent information on where to get the screening; those who do not are sent information on breast self-examination and general breast health. The promotion takes place April 23-May 1, and during that time an estimated 20,000 women are expected to be screened. CONTACT: Ann Marie Pomerincke or Pam Johns, 206/283-1152.

WESTCHESTER (County, N.Y.): The Westchester breast cancer detection program will be conducted in conjunction with other ACS Divisions in the New York City area. Sixteen hospitals and clinics in Westchester County will participate in the program, offering low-cost ($40) mammograms. In Yonkers, N.Y., on April 25, a mobile radiology unit will give mammograms for a reduced cost of $45 at St. Eugene's Church. Literature on breast health will be available at this event, and breast self-examination (BSE) will be taught. BSE will also be taught at area high schools. CONTACT: Susan Knobel, 914/949-4800.

WISCONSIN: A statewide screening project will involve approximately 100 hospitals and clinics. From April 25 to May 9 a toll-free hotline will be available for calls for information on eligibility for low-cost mammograms ($50 or less) and other breast cancer-related information. CONTACT: Marjean Jondrow, 608/294-0487.

AMERICAN CANCER SOCIETY®

# FACT SHEET FOR AVAILABLE LOW COST SCREENING MAMMOGRAPHY

## DISTRICT OF COLUMBIA DIVISION, INC.

Providence Hospital
Department of Radiology
1150 Varnum Street, N.E.
Washington, DC 20017

Cost: $25.00
Phone: 269-7958/54/72

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Howard University Hospital
Department of Radiology
2041 Georgia Avenue, N.W.
Washington, DC 20060

Cost: $25.00
Phone: 529-3601

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D.C. Imaging
2139 Georgia Avenue, N.W.
Washington, DC 20001

Cost: $50.00
Phone: 328-1400

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Washington Radiology Assoc.
2141 K Street, N.W.
Washington, DC 20037

Cost: $50.00
Phone: 223-9722

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Washington Ultrasound
8408 Arlington Blvd.
Fairfax, VA 22031

Cost: $50.00
Phone: 698-8800

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Washington Ultrasound
10215 Fernwood Road
Bethesda, MD 20817

Cost: $50.00
Phone: 564-1056

Diagnostic Radiology
2041 MLK, Jr., Ave., S.E.
Washington, DC 20020

Cost: $50.00
Phone: 889-5441

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Columbia Hospital for Women
Betty Ford Center
2425 L Street, N.W.
Washington, DC 20037

Cost: $55.00
Phone: 293-6014/15

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Drs. Groover, Christie & Merritt
4930 Del Ray Avenue
Bethesda, MD 20814

Cost: $65.00
Phone: 656-6311

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Mary Esther Center for Women
Suburban Hosptial
8600 Old Georgetown Road
Bethesda, MD 20814

Cost: $65.00
Phone: 656-6311

---

Sibley Hospital
Department of Radiology
5255 Loughboro Rd., N.W.
Washington, DC 20016

Cost: $75.00
Phone: 537-4795

NOTE: When making appointments, ask for "screening mammography."
These prices and information are subject to change without notice.

## LOW COST MAMMOGRAPHY IN MONTGOMERY COUNTY

The radiology centers listed below have agreed to offer mammograms for $50 from April 15 - May 15, 1987.

To be eligible for this reduced fee, you must meet the following criteria:

- o have no present symptoms of breast cancer
- o ages 35-39 and never had a mammogram or
- o ages 40 and over and not had a mammogram in the last 12 months

| | | |
|---|---|---|
| **BREAST IMAGING CENTER**<br>Clinical Radiologists, P.A.<br>2101 Medical Park Drive, Suite 104<br>Silver Spring, Maryland 20902 | 681-8680 | M - W 8:00 a.m. - 5:00 p.m.<br>Tu-Th 8:00 a.m. - 8:00 p.m.<br>Sat. 8:00 a.m. - 12 Noon |
| COMMUNITY RADIOLOGY ASSOCIATES<br>11120 New Hampshire Avenue<br>Suite 105<br>Silver Spring, Maryland 20904 | 681-7600 | 8:30 a.m. - 5:00 p.m. |
| 1106 Spring Street<br>Silver Spring, Maryland 20910 | 585-0983 | 8:30 a.m. - 5:00 p.m. |
| 20528 Germantown Road<br>Germantown, Maryland 20874 | 428-2884 | 8:30 a.m. - 5:00 p.m. |
| 10401 Old Georgetown Road<br>Bethesda, Maryland 20814 | 530-6646 | 8:30 a.m. - 5:00 p.m. |
| FOR WOMEN ONLY<br>The Breast Diagnostic Center<br>18111 Prince Philip Drive, #327<br>Olney, Maryland 20832 | 774-5414 | 9:00 a.m. - 5:00 p.m. |
| MONTGOMERY IMAGING CENTER<br>1201 Seven Locks Road, Suite 100<br>Rockville, Maryland 20854 | 424-1781 | 7:30 a.m. - 9:00 p.m. |
| SHADY GROVE RADIOLOGICAL CONSULTANTS, P.A.<br>19242 Montgomery Village Avenue<br>Gaithersburg, Maryland 20879 | 948-6414 | 9:00 a.m. - 5:30 p.m. |
| 50 W. Edmonston Drive<br>Rockville, MD 20852 | 762-1818 | 9:00 a.m. - 5:30 p.m. |
| WASHINGTON IMAGING CENTER<br>5550 Friendship Boulevard<br>Chevy Chase, Maryland 20815 | 951-7277 | 8:00 a.m. - 5:00 p.m. |
| WASHINGTON ULTRASOUND ASSOCIATES, P.C.<br>10215 Fernwood Road, #50<br>Bethesda, Maryland 20817 | 564-1053 | 9:00 a.m. - 5:00 p.m. |

Please call the center of your choice to make an appointment. All meet the American Cancer Society's guidelines for mammography screening.

## LOW COST MAMMOGRAPHY IN MONTGOMERY COUNTY

The radiology centers listed below have agreed to offer mammograms for $50 from April 15 - May 15, 1987.

To be eligible for this reduced fee, you must meet the following criteria:

- o have no present symptoms of breast cancer
- o ages 35-39 and never had a mammogram or
- o ages 40 and over and not had a mammogram in the last 12 months

| | | |
|---|---|---|
| BREAST IMAGING CENTER<br>Clinical Radiologists, P.A.<br>2101 Medical Park Drive, Suite 104<br>Silver Spring, Maryland 20902 | 681-8680 | M - W 8:00 a.m. - 5:00 p.m.<br>Tu-Th 8:00 a.m. - 8:00 p.m.<br>Sat. 8:00 a.m. - 12 Noon |
| COMMUNITY RADIOLOGY ASSOCIATES<br>11120 New Hampshire Avenue<br>Suite 105<br>Silver Spring, Maryland 20904 | 681-7600 | 8:30 a.m. - 5:00 p.m. |
| 1106 Spring Street<br>Silver Spring, Maryland 20910 | 585-0983 | 8:30 a.m. - 5:00 p.m. |
| 20528 Germantown Road<br>Germantown, Maryland 20874 | 428-2884 | 8:30 a.m. - 5:00 p.m. |
| 10401 Old Georgetown Road<br>Bethesda, Maryland 20814 | 530-6646 | 8:30 a.m. - 5:00 p.m. |
| FOR WOMEN ONLY<br>The Breast Diagnostic Center<br>18111 Prince Philip Drive, #327<br>Olney, Maryland 20832 | 774-5414 | 9:00 a.m. - 5:00 p.m. |
| MONTGOMERY IMAGING CENTER<br>1201 Seven Locks Road, Suite 100<br>Rockville, Maryland 20854 | 424-1781 | 7:30 a.m. - 9:00 p.m. |
| SHADY GROVE RADIOLOGICAL CONSULTANTS, P.A.<br>19242 Montgomery Village Avenue<br>Gaithersburg, Maryland 20879 | 948-6414 | 9:00 a.m. - 5:30 p.m. |
| 50 W. Edmonston Drive<br>Rockville, MD 20852 | 762-1818 | 9:00 a.m. - 5:30 p.m. |
| WASHINGTON IMAGING CENTER<br>5550 Friendship Boulevard<br>Chevy Chase, Maryland 20815 | 951-7277 | 8:00 a.m. - 5:00 p.m. |
| WASHINGTON ULTRASOUND ASSOCIATES, P.C.<br>10215 Fernwood Road, #50<br>Bethesda, Maryland 20817 | 564-1053 | 9:00 a.m. - 5:00 p.m. |

**Please call the center of your choice to make an appointment. All meet the American Cancer Society's guidelines for mammography screening.**

Appendix D

American College of Radiology

Application for Accreditation in Mammography

AMERICAN COLLEGE OF RADIOLOGY
APPLICATION FOR ACCREDITATION IN MAMMOGRAPHY

ID # _____
(for office use only)

(Please print)

Facility Name _____

Address _____

_____

Telephone number _____

Chief Physician _____

PRIVILEGED AND CONFIDENTIAL

PEER REVIEW INFORMATION

## I PRACTICE SETTING

WHERE IS MAMMOGRAPHY PRACTICE LOCATED?
(check the one location for which accreditation is sought)

|__| 1 Private office

|__| 2 Hospital

|__| 3 Multispecialty clinic

|__| 4 Mobile unit

|__| 5 Multiple settings, explain_____

_____

|__| 6 Other, specify_____

HOW MANY MAMMOGRAMS ARE BEING PERFORMED IN THIS PRACTICE LOCATION PER MONTH

|__|__|__|__|__|

PROPORTION INVOLVING SYMPTOMATIC* PATIENTS: |__|__|__|%

*(Those women with past or present clinical signs or symptoms of breast cancer)

INDICATE ANY NON MAMMOGRAPHIC BREAST IMAGING PROCEDURES WHICH ARE ALSO PERFORMED IN THIS PRACTICE LOCATION:

|__| 1 Ultrasound

|__| 2 Radiography

|__| 3 Fluoroscopy

|__| 4 CT

|__| 5 Thermography

|__| 6 Transillumination/Diaphanography

|__| 7 MRI

|__| 8 Ductography

|__| 9 Other, Specify _____

Are Non-Breast imaging procedures done in this practice location?

|__| 1 no

|__| 2 yes

NAME ALL PHYSICIANS INTERPRETING MAMMOGRAMS IN THIS PRACTICE LOCATION; INDICATE IF THEY ARE ABR CERTIFIED RADIOLOGISTS AND ANY SPECIAL TRAINING THEY HAVE HAD IN MAMMOGRAPHY (AS PART OF RESIDENCY OR FELLOWSHIP, IN WORKSHOPS, SEMINARS, SYMPOSIA ETC.) GIVE THE NUMBER OF YEARS EXPERIENCE EACH HAS HAD IN INTERPRETING MAMMOGRAMS. (YOU MUST SUBMIT CV'S FOR EACH PHYSICIAN LISTED BELOW)

| NAME (print) | SPECIFY TYPE AND LENGTH OF TRAINING IN MAMMOGRAPHY | ABR CERTIFICATION | YEARS OF EXPERIENCE IN MAMMOGRAPHY |
|---|---|---|---|
| _____ | _____ | \|_\| Yes \|_\| No | \|__\|__\| |
| _____ | _____ | \|_\| Yes \|_\| No | \|__\|__\| |
| _____ | _____ | \|_\| Yes \|_\| No | \|__\|__\| |
| _____ | _____ | \|_\| Yes \|_\| No | \|__\|__\| |
| _____ | _____ | \|_\| Yes \|_\| No | \|__\|__\| |
| _____ | _____ | \|_\| Yes \|_\| No | \|__\|__\| |

| NAME OF FULL TIME OR CONTRACT RADIOLOGICAL PHYSICIST FOR THIS PRACTICE LOCATION (print) | | BOARD CERTIFICATION | SPECIFY BOARD | SPECIFY SUBCERTIFICATION |
|---|---|---|---|---|
| _____ | _____ | \|_\| Yes \|_\| No | _____ | _____ |
| _____ | _____ | \|_\| Yes \|_\| No | _____ | _____ |
| _____ | _____ | \|_\| Yes \|_\| No | _____ | _____ |

NAME ALL INDIVIDUALS WHO ARE ACTUALLY PERFORMING MAMMOGRAPHY, INDICATE WHETHER THEY ARE CERTIFIED OR LICENSED AND ANY SPECIAL TRAINING THEY HAVE HAD IN MAMMOGRAPHY. INDICATE HOW MANY YEARS THEY HAVE BEEN TAKING MAMMOGRAMS.

| NAME (print) | SPECIFY TYPE AND LENGTH OF TRAINING IN MAMMOGRAPHY | CERTIFIED OR LICENSED | YEARS OF EXPERIENCE |
|---|---|---|---|
| _____ | _____ | \|_\| Yes \|_\| No | \|__\|__\| |
| _____ | _____ | \|_\| Yes \|_\| No | \|__\|__\| |
| _____ | _____ | \|_\| Yes \|_\| No | \|__\|__\| |
| _____ | _____ | \|_\| Yes \|_\| No | \|__\|__\| |
| _____ | _____ | \|_\| Yes \|_\| No | \|__\|__\| |
| _____ | _____ | \|_\| Yes \|_\| No | \|__\|__\| |
| _____ | _____ | \|_\| Yes \|_\| No | \|__\|__\| |
| _____ | _____ | \|_\| Yes \|_\| No | \|__\|__\| |

## III EQUIPMENT

FOR ALL MAMMOGRAPHIC MACHINES (UNITS 1,2,3,etc.) USED IN THIS PRACTICE LOCATION, PROVIDE THE INDICATED INFORMATION. IF THERE ARE MORE THAN 4 UNITS AT THIS LOCATION, USE CONTINUATION SHEET.

| UNIT | MANUFACTURER | MODEL NUMBER | DEDICATED* (YES - NO) | TARGET MATERIAL (W,Mo,W/Mo) | FILTER (MATERIAL & THICKNESS) | PHOTOTIMED (YES - NO) | NOMINAL FOCAL SPOT SIZE(mm) | FOCUS - RECEPTOR DISTANCE(cm) |
|---|---|---|---|---|---|---|---|---|
| 1 | | | | | | | | |
| 2. | | | | | | | | |
| 3. | | | | | | | | |
| 4. | | | | | | | | |

| UNIT | HVL (@ kVp) | COMPRESSION (YES - NO) | MAGNIFICATION (YES - NO) | GRID (YES - NO) | STATIONARY OR RECIPROCATING | GRID RATIO | GRID FREQUENCY (LINES/INCH OR cm) | YEAR INSTALLED |
|---|---|---|---|---|---|---|---|---|
| 1. | | | | | | | | |
| 2. | | | | | | | | |
| 3. | | | | | | | | |
| 4. | | | | | | | | |

SPECIFY TYPE OF RECORDING SYSTEM(S) USED IN THIS PRACTICE LOCATION

|__| FILM/SCREEN (Code type of each)

|__| XEROX (circle type - 125 or 175)

|__| XONICS

|__| FILM

1. KODAK MIN-R
2. KODAK OM
3. KODAK TMM
4. FUJI-MI
5. AGFA-MAMORAY
6. DUPONT LDS
7. DUPONT LDT
8. DUPONT MRF31
9. DUPONT SR329
10. OTHER

|__| SCREEN

1. KODAK MIN-R
2. KODAK MIN-R-RF
3. DUPONT LO DOSE
4. OTHER

FOR EACH PROCESSOR GIVE MANUFACTURER, MODEL NUMBER, CHEMISTRY TYPE, TEMPERATURE AND TIME AT WHICH PROCESSING IS DONE

| MANUFACTURER | MODEL NUMBER | CHEMISTRY TYPE | TEMPERATURE | TIME |
|---|---|---|---|---|
| | | | | |
| | | | | |
| | | | | |
| | | | | |

(*Dedicated: Equipment specifically designed for mammography)

## IV TECHNIQUES

WHICH VIEW(S) COMPRISE A TYPICAL EXAM?

C.C. _____ ML _____

OBL _____ OTHER _____ (SPECIFY)

PROVIDE TYPICAL TECHNIQUE FACTORS EMPLOYED FOR A C.C. VIEW OF AN AVERAGE DENSITY 4.5CM COMPRESSED BREAST (FOR EACH MAMMOGRPAHY UNIT DESCRIBED ABOVE)

| Unit | kVp | mA & TIME (OR mAs) | GRID USED (yes - no) |
|---|---|---|---|
| 1 | | | |
| 2. | | | |
| 3. | | | |
| 4. | | | |

## V QUALITY ASSURANCE PROGRAM

INDICATE HOW FREQUENTLY EACH OF THE FOLLOWING IS CHECKED AND WHO IS RESPONSIBLE FOR CHECKING, I.E., PHYSICIST ETC. (Check all boxes that apply). *IN THE CASES OF DOSE AND HVL, INDICATE THE MOST RECENT MEASURED VALUE AND THE DATE OF MEASUREMENT. IF TWO SYSTEMS IN USE, PLEASE COPY SECTION.

| | FREQUENCY | | | | | | | | | RESPONSIBILITY | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | R | P | T | S |
| *AVERAGE GLANDULAR DOSE _____ | | | | | | | | | | | | | |
| +MAMMOGRAPHIC PHANTOM IMAGE QUALITY | | | | | | | | | | | | | |
| *BEAM QUALITY (HALF VALUE LAYER)_____ | | | | | | | | | | | | | |
| kVp ACCURACY | | | | | | | | | | | | | |
| TIMER ACCURACY | | | | | | | | | | | | | |
| CONSISTENCY OF VARIOUS mA STATIONS | | | | | | | | | | | | | |
| FOCAL SPOT SIZE | | | | | | | | | | | | | |
| THICKNESS INDICATORS | | | | | | | | | | | | | |
| GRID | | | | | | | | | | | | | |
| PHOTOTIMER (AUTOMATIC EXPOSURE CONTROL) | | | | | | | | | | | | | |
| CONSISTENCY OF OUTPUT (mR AT A FIXED DISTANCE) | | | | | | | | | | | | | |
| SCREENS | | | | | | | | | | | | | |
| FILM/SCREEN CONTACT | | | | | | | | | | | | | |
| PROCESSOR SENSITOMETRY | | | | | | | | | | | | | |
| DARKROOM/SAFELIGHTS | | | | | | | | | | | | | |
| RETAKE RATE | | | | | | | | | | | | | |
| PROPER FUNCTIONING OF THE COLLIMATOR | | | | | | | | | | | | | |
| DARK DUSTING (XEROX ONLY) | | | | | | | | | | | | | |
| PROCESSOR SERVICE (XEROX ONLY) | | | | | | | | | | | | | |
| IMAGE AUDIT (XEROX ONLY) | | | | | | | | | | | | | |

FREQUENCY

0 = Not done
1 = At installation
2 = When repaired
3 = As needed
4 = Daily
5 = Weekly
6 = Monthly
7 = Quarterly
8 = Yearly
9 = Other

RESPONSIBILITY

R =Radiologist
P = Physicist
T = Technologist
S = Service person

+PHANTOM MANUFACTURER AND MODEL _____

## VI MEDICAL HISTORY

IS A HISTORY TAKEN AS PART OF THE MAMMOGRAPHIC PROCEDURE?

|__| 1 No 2 Yes

INDICATE WHICH OF THE FOLLOWING ARE PART OF THE HISTORY

0 not applicable - 1 no - 2 yes

|__| NOT APPLICABLE (NOT DONE)
|__| CURRENT BREAST SYMPTOMS (mass, bloody nipple discharge, dimpling, etc.)
|__| PRIOR BREAST CANCER, when _____
|__| FAMILY HISTORY (mother, sister with breast cancer and if pre or post menopausal)
|__| AGE AT ONSET AND CESSATION OF MENSES
|__| PRESENT MENSTRUAL STATUS
(Pre menopausal, Peri menopausal, Post menopausal)
|__| HORMONE INGESTION
(Birth control pills, menopausal symptoms, fertility drugs etc.)
|__| RADIATION TREATMENT TO BREASTS
|__| PRIOR MALIGNANCIES
|__| PREVIOUS MAMMOGRAM, when _____
|__| BENIGN BREAST DISEASE
|__| AGE AT FIRST LIVE BIRTH
|__| NULLIPARITY
|__| ANY PREVIOUS BREAST SURGERY, when _____

## VII PHYSICAL EXAMINATION

WHO IS RESPONSIBLE FOR DOING THE PHYSICAL EXAMINATION?

|__|
0 Not applicable (not done)
1 Radiologist who interprets mammogram
2 Radiologist (not necessarily interpreter)
3 Other physician
4 Technologist who performs mammogram
5 Nurse
6 Other

HAS THE PERSON PERFORMING THE PHYSICAL RECEIVED ANY SPECIAL TRAINING SPECIFIC TO BREAST EXAMINATION?

|__|
0 Not applicable (not done)
1 No
2 Yes, explain_____

IS THE PATIENT INSTRUCTED IN BREAST SELF EXAMINATION DURING THE PHYSICAL EXAMINATION OR AT ANY TIME?

|__|
1 No
2 Yes, explain who gives instruction_____
(job title)

DOES THE REPORT INCLUDE ALL FINDINGS, MAMMOGRAPHIC AND CLINICAL?

|__| 0 Not applicable, no clinical exam done
1 No, mammographic findings only
2 Yes, all findings are reported

IN THE ABSENCE OF MAMMOGRAPHIC FINDINGS, IS A RECOMMENDATION MADE ON THE BASIS OF THE CLINICAL EXAMINATION?

|__| 0 Not applicable, no clinical exam done
1 No, mammographic findings only
2 Yes, all findings are reported

IS THERE A MECHANISM IN PLACE FOR FOLLOWUP ON POSITIVE OR EQUIVOCAL RESULTS (I.E., TO ASSURE THAT PATIENT'S PHYSICIAN HAS RECEIVED REPORT AND UNDERSTANDS RECOMMENDATIONS IF ANY)?

|__| 1 No
2 Yes, explain _____

ARE PATIENTS WHO HAVE EQUIVOCAL RESULTS CONTACTED FOR A FOLLOWUP EXAMINATION AT A PRESCRIBED TIME, E.G., 6 MONTHS, ETC.?

|__| 1 No, patient's physician has responsibility for followup
2 Yes, all patients are sent a notice when the followup exam is due



HOW ARE SELF REFERRED PATIENTS HANDLED IN TERMS OF SENDING A REPORT? (Check all that apply)

|__| N/A, All patients are referred
|__| Each patient must supply the name of a physician
|__| Patient may select a physician from an available pool
|__| Patient receives the report in the absence of a physician
|__| Patient & Physician (if any) always receive report.

ARE ANY FOLLOWUP MECHANISMS IN PLACE TO DETERMINE:

**1 no - 2 yes**

|__| Results of biopsies
|__| Number of cancers with negative mammograms
|__| Number of cancers with positive mammograms
|__| Number of minimal cancers detected
|__| Number of cancers detected by mammography alone
|__| Number of cancers detected by physical exam alone
|__| Number of cancers detected by both mammography and physical exam
|__| Number of mammographic localizations with positive results
|__| Number of positve mammograms without evidence of cancer

IN WHAT PROPORTION OF CASES ARE ADDITIONAL VIEWS DONE? |__|__|__|%

IN WHAT PROPORTION OF CASES ARE ADDITIONAL IMAGING EXAMS TESTS ORDERED? |__|__|__|%

SPECIFY TYPES OF EXAMS ORDERED. _____

**IX IS THERE A POLICY FOR FILM RETENTION?**

|__| 1 No
2 Yes (Length of time = _____)

**X IF ACCREDITATION IS GRANTED, INDICATE CORRECT INDIVIDUAL OR CORPORATE NAME DESIRED ON CERTIFICATE.**

_____

Please return this questionnaire to:

Mammography Accreditation Department
American College of Radiology
1891 Preston White Drive
Reston, VA 22091

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